

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BAYER HEALTHCARE AG, ALCON, INC. )	)	
and ALCON RESEARCH, LTD., )	)	
	)	
Plaintiffs, )	)	
	)	
v. )	)	C. A. No. 06-234-SLR
	)	
TEVA PHARMACEUTICALS USA, INC., )	)	
	)	
Defendant. )	)	

**JOINT PRETRIAL ORDER**

Plaintiffs Bayer HealthCare AG and Bayer Pharmaceuticals Corporation (collectively “Bayer”), Plaintiffs Alcon, Inc. and Alcon Research, Ltd. (collectively “Alcon”) and Defendant Teva Pharmaceuticals USA, Ltd. (“Teva”), by their undersigned counsel, submit this proposed Joint Pretrial Order pursuant to Local Rule 16.3. A Pretrial Conference in this matter is scheduled for February 12, 2008 at 2:00 p.m. Trial of this matter is scheduled to begin on February 25, 2008.

**I. NATURE OF THE ACTION AND PLEADINGS**

1. These are two consolidated patent infringement actions arising out of Teva’s filing with the United States Food and Drug Administration of two separate Abbreviated New Drug Applications (“ANDA”), pursuant to the Federal Food, Drug and Cosmetic Act, seeking approval to commercially manufacture, use, or sell generic drug products prior to the expiration of various U.S. patents.

2. Bayer sells a tablet drug product under the tradename Avelox<sup>®</sup>. Bayer HealthCare AG is the owner of U.S. Patent Nos. 4,990,517 (the “517 patent”) and 5,607,942 (the “942 patent”), which are listed in the Orange Book for Avelox<sup>®</sup> tablets.

3. Alcon sells a topical ophthalmic pharmaceutical composition under the tradename Vigamox<sup>®</sup>. Alcon, Inc. is the owner of U.S. Patent No. 6,716,830 (the “‘830 patent”), which, along with the ‘517 and ‘942 patents, is listed in the Orange Book for Vigamox<sup>®</sup> topical ophthalmic solution. Alcon, Inc. is a licensee under the ‘517 and ‘942 patents.

4. On April 5, 2006, Bayer HealthCare AG and Alcon filed a Complaint for infringement of the ‘517, ‘942, and ‘830 patents against Teva, alleging that Teva’s filing of its ANDA No. 78-073 for the purpose of obtaining approval to commercially manufacture, use, or sell a generic equivalent of Vigamox<sup>®</sup> prior to the expiration of the ‘517, ‘942, and ‘830 patents constitutes acts of infringement of the ‘517, ‘942, and ‘830 patents. Bayer HealthCare AG and Alcon seek a judgment providing that the effective date of any FDA approval for Teva to commercially make, use, or sell the drug product that is the subject of ANDA No. 78-073 or any topical ophthalmic pharmaceutical composition containing moxifloxacin or any pharmaceutically useful acid addition salt thereof in a concentration of 0.1 to 1.0 wt % and a pharmaceutically acceptable vehicle therefor be not earlier than the latest of the expiration dates of the ‘517, ‘942, and ‘830 patents. Bayer and Alcon also seek an injunction against any infringement or inducement of infringement by Teva of the ‘517, ‘942, and ‘830 patents, together with costs, expenses, and attorney’s fees, and such other and further relief as the Court may deem just and proper. The action was subsequently docketed as No. 06-234-SLR.

5. On April 28, 2006, Teva filed its Answer, denying infringement of the ‘517, ‘942, and ‘830 patents and alleging that the claims of the ‘517, ‘942, and ‘830 patents are invalid. Teva seeks a judgment that the April 5, 2006 Complaint be dismissed with prejudice and that the manufacture, use, import, or sale of the drug product that is the subject of ANDA No. 78-073 product will not infringe any valid and enforceable claim of the ‘517, ‘942, or ‘830 patents. Teva

also seeks costs, expenses, attorney's fees, and such additional relief as the Court deems just and proper.

6. On March 7, 2007, Teva notified Bayer Corp. and Bayer HealthCare AG that it had amended its ANDA No. 77-437 for a generic equivalent of Avelox<sup>®</sup> tablets to contain a paragraph IV certification with respect to the '517 and '942 patents. On April 5, 2007, Bayer filed a Complaint for infringement of the '517 and '942 patents against Teva, alleging that Teva's filing of its ANDA No. 77-437 for the purpose of obtaining approval to commercially manufacture, use, or sell a generic equivalent of Avelox<sup>®</sup> prior to the expiration of the '517 and '942 patents constitutes acts of infringement of the '517 and '942 patents. Bayer seeks a judgment providing that the effective date of any FDA approval for Teva to commercially make, use, or sell moxifloxacin or any pharmaceutically utilizable acid addition salt thereof, the drug product that is the subject of ANDA No. 77-437, or any drug product containing moxifloxacin or any pharmaceutically useful acid addition salt thereof be not earlier than the latest of the expiration dates of the '517 and '942 patents. Bayer also seeks an injunction against any infringement or inducement of infringement by Teva of the '517 and '942 patents, together with costs, expenses, and attorney's fees, and such other and further relief as the Court may deem just and proper. The action was subsequently docketed as No. 07-195-SLR.

7. On April 24, 2007, Teva filed its Answer, denying infringement of the '517 and '942 patents and alleging that the claims of the '517 and '942 patents are invalid. Teva seeks a judgment dismissing the April 5, 2007 Complaint with prejudice and that the manufacture, use, import, or sale of the drug product that is the subject of ANDA No. 77-437 product will not infringe any valid and enforceable claim of the '517 or '942 patents. Teva also seeks costs, expenses, attorney's fees, and such additional relief as the Court deems just and proper.

8. On April 27, 2007, the parties jointly moved to consolidate the two actions, Nos. 06-234-SLR and 07-195-SLR, and the Court ordered the actions consolidated on May 11, 2007.

9. On August 2, 2007, the parties filed a Stipulation that Teva could file Amended Answers in each action subject to the Court's approval, and the Court signed the Stipulation on August 3, 2007. On August 3, 2007, pursuant to the Stipulation, Teva filed its Amended Answers under seal, in which it added the affirmative defense that the '942 patent is unenforceable due to inequitable conduct. Teva also amended its Answers to seek a judgment that the '942 patent is unenforceable due to inequitable conduct.

10. With respect to the drug product that is the subject of ANDA No. 77-437, Bayer is asserting infringement in this action of Claims 1, 2, 8, 9, and 11 of the '517 patent and Claims 1, 2, 3, 4, 5, and 7 of the '942 patent. With respect to the drug product that is the subject of ANDA No. 78-073, Bayer and Alcon are asserting infringement in this action of Claims 1, 2, 8 and 11 of the '517 patent, Claims 1, 2, 3, 4, 5, and 7 of the '942 patent, and Claim 1 of the '830 patent.

11. By Stipulation filed July 24, 2007 and signed by the Court on July 25, 2007, and as more fully set forth in the parties' Statement of Admitted Facts Requiring No Proof, the parties have reached stipulations regarding aspects of Plaintiffs' infringement case and Teva's noninfringement defenses.

12. With respect to the '517 patent, Teva has asserted that its proposed ANDA products do not infringe the asserted claims. With respect to the '942 patent, Teva has asserted that its proposed ANDA products do not infringe the asserted claims, that the asserted claims are invalid for double patenting over the '517 patent, that claims 1, 3, and 5 are invalid for indefiniteness, and that the '942 patent is unenforceable due to inequitable conduct. With respect to the '830 patent,



Teva has asserted that the drug product which is the subject of ANDA No. 78-073 does not infringe claim 1, that claim 1 is invalid as anticipated by and obvious in light of the prior art, and that claim 1 is invalid for failure to satisfy the best mode, written description, and enablement requirements of 35 U.S.C. § 112.

## **II. BASIS FOR FEDERAL JURISDICTION**

1. This action arises under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

2. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b). No party contests venue.

## **III. STATEMENT OF ADMITTED FACTS REQUIRING NO PROOF**

1. The parties' Statement of Admitted Facts Requiring No Proof is attached as Exhibit 1.

## **IV. STATEMENTS OF ISSUES OF FACT REMAINING TO BE LITIGATED**

1. Bayer and Alcon's Statement of Issues of Fact Which Remain to be Litigated is attached as Exhibit 2.

2. Teva's Statement of Issues of Fact Which Remain to be Litigated is attached as Exhibit 3.

## **V. STATEMENTS OF ISSUES OF LAW REMAINING TO BE LITIGATED**

1. Bayer and Alcon's Statement of Issues of Law Which Remain to be Litigated is attached as Exhibit 4.

2. Teva's Statement of Issues of Law Which Remain to be Litigated is attached as Exhibit 5.

## **VI. EXHIBITS**

1. Bayer and Alcon's list of exhibits it may offer at trial and Teva's objections thereto is attached as Exhibit 6.

2. Teva's list of exhibits it may offer at trial and Bayer and Alcon's objections thereto is attached as Exhibit 7.

3. The parties reserve the right to supplement these exhibit lists, with sufficient and reasonable notice to the other side.

4. The parties will offer at trial one or more of the exhibits set forth in their respective exhibit lists. These lists include the exhibit numbers to be used at trial and a description sufficient to identify the exhibits. These exhibit lists may include exhibits that may not necessarily be offered or introduced into evidence.

5. Each party may use an exhibit that is listed on the other side's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to evidentiary objections.

6. The listing of a document on a party's exhibit list is not an admission that such document is relevant or admissible when offered by the opposing side for the purpose that the opposing side wishes to admit the document. Each party reserves the right to object to the relevancy of any evidence offered by the other party, at the time such evidence is offered, in view of the specific context in which such evidence is offered.

7. The parties will exchange color representations, on 8-1/2 by 11 paper, of demonstrative exhibits intended to be used at trial, except for demonstrative exhibits used for impeachment, at such times and places and under such circumstances as mutually agreed to by

the parties. The notice provisions of this paragraph shall not apply to demonstrative exhibits created in the courtroom during testimony at trial or the enlargement, simple highlighting, ballooning, or excerption of trial exhibits or testimony.

8. The parties have agreed that demonstrative exhibits the parties intend to use at trial do not need to be included on their respective lists of trial exhibits.

9. The parties shall make available for inspection any physical exhibits to be used at trial, labeled with the exhibit number. Access to the opposing side's physical exhibits shall be at such time and place and under such circumstances as are reasonable and mutually agreed to.

## **VII. WITNESSES TO BE CALLED IN PERSON OR BY DEPOSITION**

1. The list of witnesses who Bayer and Alcon intend to call to testify at trial, either in person or by deposition, and the specialties of experts to be called as witnesses, is attached as Exhibit 8. For witnesses whose testimony will be by deposition, a list of designations is provided.

2. The list of witnesses who Teva intends to call to testify at trial, either in person or by deposition, and the specialties of experts to be called as witnesses, is attached as Exhibit 9. For witnesses whose testimony will be by deposition, a list of designations is provided.

3. The parties agree to give one another advance notice of the anticipated order of their witnesses' testimony at such times as will be mutually agreed by the parties.

4. With respect to deposition designations and counter-designations, each side shall be charged only with the time needed to read its own designations or counter-designations, and will not be charged with the time necessary to read the other side's designations or counter-designations.

5. The listing of a witness on a party's witness list does not require that party to call that witness to testify, either in person or by deposition.

#### **VIII. THE PARTIES' BRIEF STATEMENTS OF INTENDED PROOFS**

1. Bayer and Alcon's Statement of Intended Proofs is attached as Exhibit 10.
2. Teva's Statement of Intended Proofs is attached as Exhibit 11.

#### **IX. AMENDMENTS TO PLEADINGS**

Pursuant to the agreement of the parties recited in Section 1.9, no amendments to the pleadings are required.

#### **X. CERTIFICATION OF TWO-WAY COMMUNICATION**

The parties certify that two-way communication has occurred between persons having authority in a good faith effort to explore the resolution of this controversy by settlement. It was determined that the matter could not be resolved at that juncture by settlement.

#### **XI. MISCELLANEOUS ISSUES**

1. Each side be allowed a one hour opening statement.
2. A list of miscellaneous issues that Bayer and Alcon wish to address at the Pretrial Conference is attached as Exhibit 12.
3. A list of miscellaneous issues that Teva wishes to address at the Pretrial Conference is attached as Exhibit 13.

#### **XII. ORDER TO CONTROL COURSE OF ACTION**

This Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

SO ORDERED this \_\_\_\_\_ day of February, 2008.

---

Sue L. Robinson  
United States District Judge

JOINTLY SUBMITTED BY

/s/ Frederick L. Cottrell, III

Frederick L. Cottrell, III (#2555)  
cottrell@rlf.com  
Jeffrey L. Moyer (#3309)  
moyer@rlf.com  
Anne Shea Gaza (#4093)  
gaza@rlf.com  
RICHARDS, LAYTON & FINGER, P.A.  
One Rodney Square  
920 North King Street  
Wilmington, Delaware 19801  
(302) 651-7700 (telephone)  
(302) 651-7701 (facsimile)

OF COUNSEL:

Bruce R. Genderson  
Adam L. Perlman  
David I. Berl  
Dov P. Grossman  
Stanley E. Fisher  
WILLIAMS & CONNOLLY LLP  
725 Twelfth Street, N.W.  
Washington, DC 20005  
(202) 434-5000 (telephone)  
(202) 434-5029 (facsimile)

Attorneys for Plaintiffs  
Bayer HealthCare AG,  
Bayer Pharmaceuticals, Corp.,  
Alcon, Inc. and  
Alcon Research, Ltd.

/s/ Richard D. Kirk

Richard D. Kirk (#0922)  
rkirk@bayardfirm.com  
Ashley B. Stitzer (#3891)  
astitzer@bayardfirm.com  
Bayard, P.A.  
222 Delaware Ave., Suite 900  
P.O. Box 25130  
Wilmington, DE 19899  
(302) 655-5000 (telephone)

OF COUNSEL:

Bruce M. Gagala  
M. Daniel Hefner  
Douglas A. Robinson  
LEYDIG, VOIT & MAYER, LTD.  
Two Prudential Plaza  
180 N. Stetson Avenue, Suite 4900  
Chicago, IL 60601  
(312) 616-5600 (telephone)  
(312) 616-5700 (facsimile)

Attorneys for Defendant  
Teva Pharmaceuticals USA, Inc.

Dated: February 5, 2008

# EXHIBIT 1

**EXHIBIT 1**

**STATEMENT OF ADMITTED FACTS REQUIRING NO PROOF**

1. Bayer HealthCare AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having its principal place of business at D-51368 Leverkusen, Federal Republic of Germany.
2. Bayer Pharmaceuticals Corporation is a United States corporation incorporated under the laws of the State of Delaware, and having its principal place of business at 400 Morgan Lane, West Haven, Connecticut 06516.
3. Alcon, Inc. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Bösch 69, CH-6331 Hünenberg, Switzerland.
4. Alcon Manufacturing, Ltd. has been merged into Alcon Research, Ltd., a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.
5. Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.
6. United States Patent No. 4,990,517 (“the ’517 patent”) issued on February 5, 1991.
7. United States Patent Application No. 07/375,434 (“the ’434 application”), the U.S. patent application that matured into the ’517 patent, was filed in the U.S. Patent & Trademark Office (“PTO”) on June 30, 1989.



8. The '434 application claims priority to German patent application No. 3824072.6 filed on July 15, 1988 and to German patent application No. 3906365.8 filed on March 1, 1989 (the "German Priority Applications").

9. For purposes of this action, the priority date of the '517 patent is July 15, 1988.

10. United States Patent No. 5,607,942 ("the '942 patent") issued on March 4, 1997.

11. United States Patent Application No. 406,448 ("the '448 application"), the U.S. patent application that ultimately matured into the '942 patent, was filed in the U.S. Patent & Trademark Office ("PTO") on March 20, 1995.

12. The '448 application claims priority, through the '434 application, to the German Priority Applications.

13. For purposes of this action, the priority date of the '942 patent is July 15, 1988.

14. On March 5, 1993 Bayer filed U.S. Patent Application No. 08/026,906 as a continuation-in-part of U.S. Patent Application No. 07/737,631, filed July 30, 1991. Application No. 08/026,906 was abandoned after the '448 application was filed.

15. United States Patent No. 6,716,830 ("the '830 patent") issued on April 6, 2004.

16. United States Patent Application No. 10/200,868 ("the '868 application"), the U.S. patent application that ultimately matured into the '830 patent, was filed in the U.S. Patent & Trademark Office ("PTO") on July 22, 2002.

17. The '868 application claims priority, through United States Patent Application No. 09/646,797 (filed as application No. PCT/US99/22622 on September 29, 1999), to United States Provisional Patent Application No. 60/102,506 (filed on September 30, 1998) and United States Provisional Patent Application No. 60/102,504 (filed on September 30, 1998).

18. For purposes of this action, the effective filing date of the '830 patent is September 30, 1998.

19. Bayer AG was the assignee of the applications leading to the '517 patent and the '942 patent during their prosecution at the United States Patent and Trademark Office.

20. Bayer AG has assigned the '517 and '942 patents to Bayer HealthCare AG, which now owns the '517 and '942 patents.

21. Alcon, Inc. was assigned the '830 patent and owns the '830 patent.

22. Bayer Pharmaceuticals Corp. has been granted a license under the '517 and '942 patents.

23. Alcon, Inc. has been granted a license under the '517 and '942 patents.

24. Alcon Manufacturing, Ltd. (now Alcon Research, Ltd.) has been granted an exclusive license under the '830 patent.

25. Bayer sells a quinolone tablet antibacterial drug product under the tradename Avelox®.

26. Alcon sells a topical ophthalmic pharmaceutical solution under the tradename Vigamox®.

27. Bayer Pharmaceuticals Corp. is the holder of a U.S. Food and Drug Administration ("FDA") approved New Drug Application for Avelox®. Bayer has listed the '517 and '942 patents in the FDA's Orange Book for this product..

28. Alcon, Inc. is the holder of an FDA-approved New Drug Application for Vigamox®. Alcon has listed the '517, '942, and '830 patents in the FDA's Orange Book for this product.

29. On or about December 10, 2004, Teva filed an Abbreviated New Drug Application (“ANDA”), ANDA No. 77-437, with the FDA, entitled Moxifloxacin Hydrochloride Tablets, Eq. 400 mg base, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) seeking approval to commercially manufacture, use, or sell a generic equivalent of Avelox® upon expiration of the ’517 and ’942 patents.

30. On or about December 25, 2005, Teva filed an Abbreviated New Drug Application (“ANDA”), ANDA No. 78-073, with the FDA, entitled Moxifloxacin Hydrochloride Ophthalmic Solution, 0.5% as base, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking approval to commercially manufacture, use, or sell a generic equivalent of Vigamox® prior to the expiration of the ’517, ’942, and ’830 patents.

31. On or about March 7, 2007, Teva filed a Revised Patent Certification to the ’517 and ’942 patents for ANDA No. 77-437 with the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking approval to commercially manufacture, use, or sell a generic equivalent of Avelox® prior to the expiration of the ’517 and ’942 patents.

32. As used in paragraphs 32-57, the terms “infringe” and “infringes” mean either literal infringement or infringement under the doctrine of equivalents. It is agreed, however, that Teva expressly reserves its right to argue that Bayer or Alcon is estopped from asserting the doctrine of equivalents.

33. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva’s ANDA No. 77-437 infringes claim 1 of the ’517 patent, then that product also infringes each of claims 2, 8, and 9 of the ’517 patent.

34. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva’s ANDA 77-437 infringes claim 1 of the ’517 patent, then the use of that product

in accord with any label submitted in Teva's ANDA No. 77-437 infringes each of claims 1, 2, 8, 9, and 11 of the '517 patent.

35. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 infringes claim 1 of the '517 patent, then that product also infringes each of claims 2 and 8 of the '517 patent.

36. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA 78-073 infringes claim 1 of the '517 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 78-073 infringes each of claims 1, 2, 8, and 11 of the '517 patent.

37. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 77-437 infringes claim 1 of the '942 patent, then that product also infringes claim 3 of the '942 patent.

38. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA 77-437 infringes claim 1 of the '942 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 77-437 infringes each of claims 1, 3, and 5 of the '942 patent.

39. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 77-437 infringes claim 2 of the '942 patent, then that product also infringes claim 4 of the '942 patent.

40. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA 77-437 infringes claim 2 of the '942 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 77-437 infringes each of claims 2, 4, and 7 of the '942 patent.

41. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 infringes claim 1 of the '942 patent, then that product also infringes claim 3 of the '942 patent.

42. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA 78-073 infringes claim 1 of the '942 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 78-073 infringes each of claims 1, 3, and 5 of the '942 patent.

43. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 infringes claim 2 of the '942 patent, then that product also infringes claim 4 of the '942 patent.

44. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA 78-073 infringes claim 2 of the '942 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 78-073 infringes each of claims 2, 4, and 7 of the '942 patent.

45. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 contains "moxifloxacin" as used in claim 1 of the '830 patent, or an equivalent thereof, then that product infringes claim 1 of the '830 patent.

46. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 77-437 does not infringe claim 1 of the '517 patent, then that product also does not infringe claims 2, 8, and 9 of the '517 patent.

47. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 77-437 does not infringe claim 1 of the '517 patent, then the use of

that product in accord with any label submitted in Teva's ANDA No. 77-437 does not infringe claims 1, 2, 8, 9, and 11 of the '517 patent.

48. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 does not infringe claim 1 of the '517 patent, then that product also does not infringe claims 2 and 8 of the '517 patent.

49. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 does not infringe claim 1 of the '517 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 78-073 does not infringe claims 1, 2, 8, and 11 of the '517 patent.

50. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 77-437 does not infringe claim 1 of the '942 patent, then that product also does not infringe claim 3 of the '942 patent.

51. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 77-437 does not infringe claim 1 of the '942 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 77-437 does not infringe claims 1, 3, and 5 of the '942 patent.

52. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 77-437 does not infringe claim 2 of the '942 patent, then that product also does not infringe claim 4 of the '942 patent.

53. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 77-437 does not infringe claim 2 of the '942 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 77-437 does not infringe claims 2, 4, and 7 of the '942 patent.

54. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 does not infringe claim 1 of the '942 patent, then that product also does not infringe claim 3 of the '942 patent.

55. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 does not infringe claim 1 of the '942 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 78-073 does not infringe claims 1, 3, and 5 of the '942 patent.

56. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 does not infringe claim 2 of the '942 patent, then that product also does not infringe claim 4 of the '942 patent.

57. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 does not infringe claim 2 of the '942 patent, then the use of that product in accord with any label submitted in Teva's ANDA No. 78-073 does not infringe claims 2, 4, and 7 of the '942 patent.

58. If the Court determines that the moxifloxacin hydrochloride product that is the subject of Teva's ANDA No. 78-073 does not contain "moxifloxacin" as used in claim 1 of U.S. Patent No. 6,716,830 ("the '830 patent"), or an equivalent thereof, then that product does not infringe claim 1 of the '830 patent.

59. Teva Pharmaceuticals USA, Ltd. is a wholly-owned subsidiary of Teva Pharmaceuticals Industries, Ltd.

60. Novopharm Ltd., a Canadian company, is a wholly-owned subsidiary of Teva Pharmaceuticals Industries, Ltd.

61. For purposes of this action, the '517 patent is valid and enforceable.

62. On November 28, 2007, the Court issued a judgment that the active pharmaceutical ingredient of ANDA No. 76-938, held by Dr. Reddy, infringes claims 1 and 2 of the '517 patent and claims 1 and 2 of the '942 patent. Dr. Reddy's did not contest infringement or raise any issue regarding claim construction or indefiniteness. The judgment was not appealed.

63. The active pharmaceutical ingredient of ANDA No. 76-938 is described in Dr. Reddy's Drug Master File No. 16999 for Moxifloxacin Hydrochloride, which was submitted to the Food and Drug Administration on December 2, 2003.

64. The drug products that are the subject of Teva's ANDA Nos. 77-437 and 78-073 are manufactured using the same active pharmaceutical ingredient as Reddy's ANDA No. 76-938, described in Drug Master File No. 16999, which Dr. Reddy's supplies to Teva.

65. The pages bearing the following bates numbers are from Dr. Reddy's Drug Master File No. 16999 for Moxifloxacin Hydrochloride, which was submitted to the Food and Drug Administration on December 2, 2003:

DRLMOX 000001 – DRLMOX 000011  
DRLMOX 000059 – DRLMOX 000798  
DRLMOX 000913 – DRLMOX 000942  
DRLMOX 000945 – DRLMOX 001034

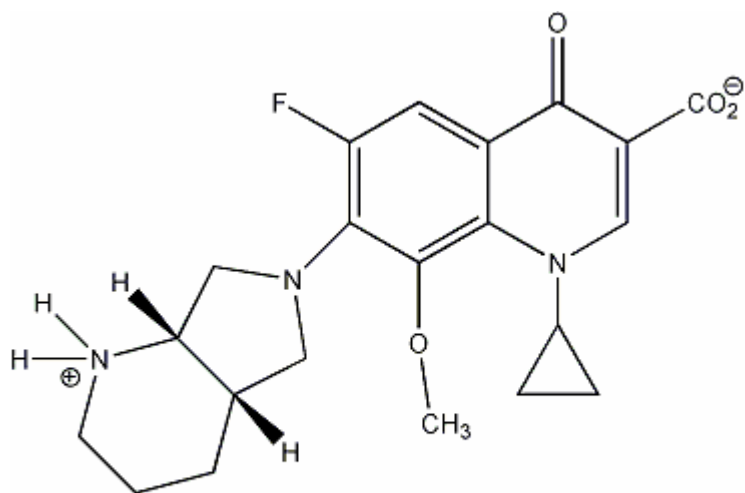
66. The pages bearing the following bates numbers are from Dr. Reddy's Abbreviated New Drug Application No. 76-938 for Moxifloxacin Hydrochloride tablets:

DRLMOX 005020  
DRLMOX 005049 – DRLMOX 005058

67. Moxifloxacin, being an amino acid, may exist as a zwitterion or betaine. In that form, the carboxylic acid is deprotonated, while the piperidine nitrogen of the bicyclic amine at position 7 of the quinolone is protonated. Accordingly, the piperidine nitrogen bears a positive

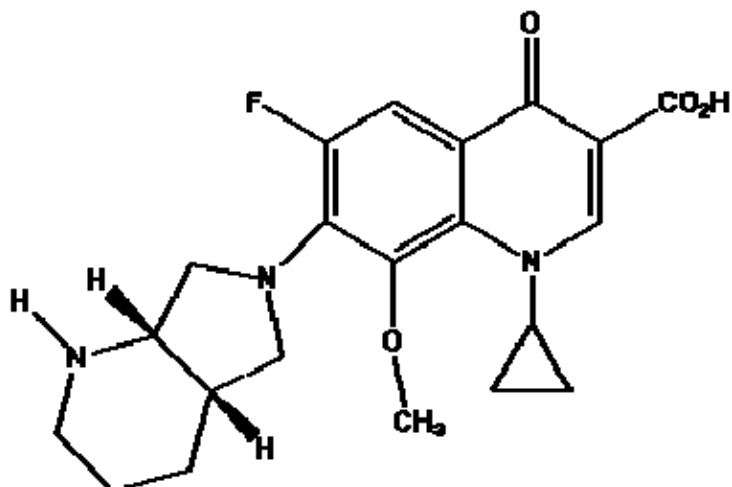


charge, while the carboxylate bears a negative charge. Moxifloxacin betaine may be depicted as follows:



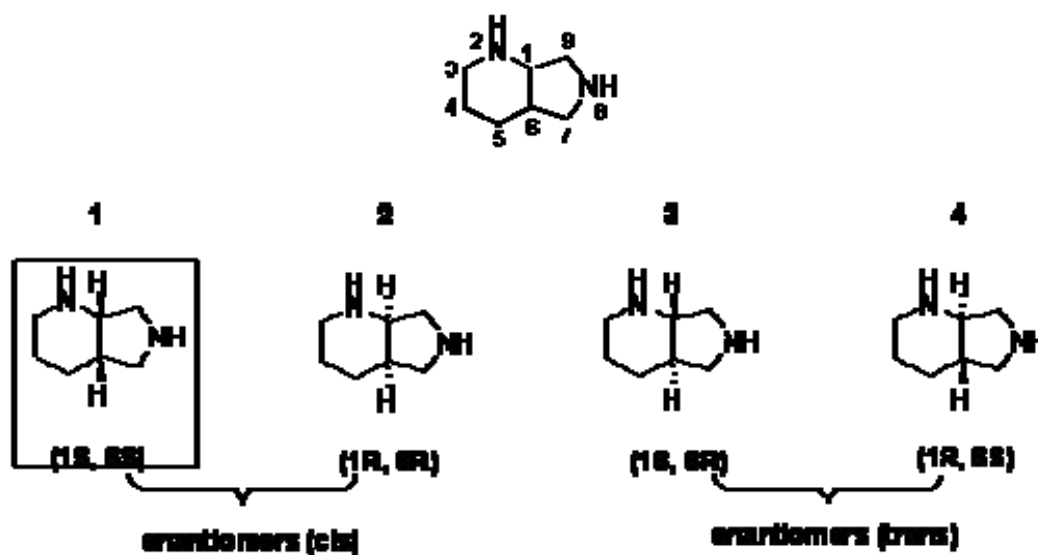
### Betaine of Moxifloxacin

Moxifloxacin betaine also may be depicted as follows (other depictions have also been used):



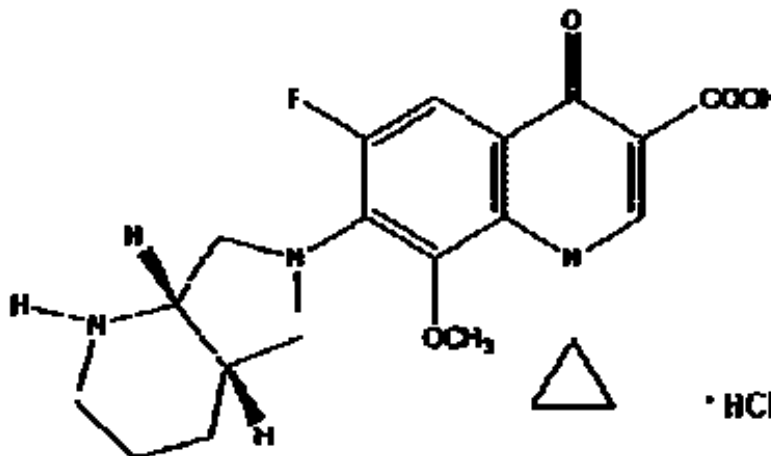
68. The bicyclic amine portion of moxifloxacin has two chiral carbons. Thus, there are four possible stereochemical arrangements for this molecule, as is shown below. Two of these compounds are cis isomers, meaning that the hydrogen atoms on the carbons shared by the two rings are on the same side of the molecule. That is, both hydrogen atoms are either above the plane of the paper or below the plane of the paper. The cis isomers are depicted as structures

1 and 2 as shown below. The other two compounds are trans isomers, meaning that the hydrogen atoms on the carbons shared by the two rings are on opposite sides of the molecule. The two possible trans isomers are depicted as structures 3 and 4 shown below. The two cis compounds, having opposite configurations at the two chiral carbons, constitute a pair of enantiomers. Likewise, the two trans compounds, having opposite configurations at the two chiral carbons, constitute a second pair of enantiomers. Compound 1 below, which is the S,S-enantiomer, is the 7-position bicycle in moxifloxacin.

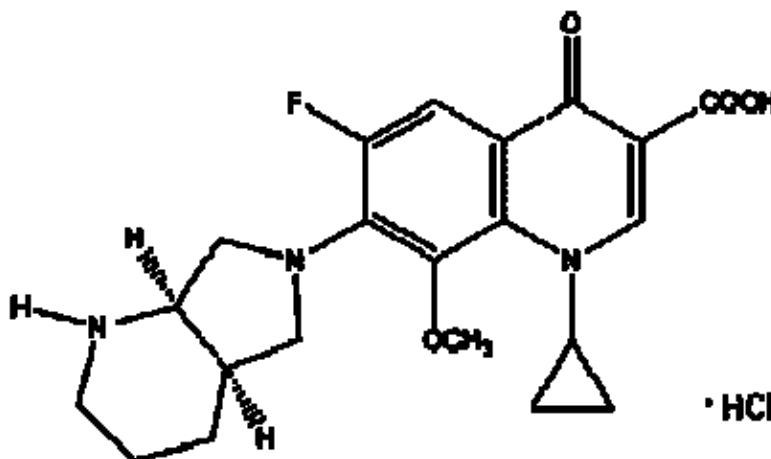


69. Moxifloxacin hydrochloride is the hydrochloride salt of moxifloxacin betaine.

Moxifloxacin hydrochloride may be depicted as follows (other depictions have also been used):



70. Moxifloxacin has an S,S configuration of hydrogens at the chiral carbons in the 7-position bicyclic amine. The corresponding compound with the R,R configuration of hydrogens (“the R,R enantiomer”) may be depicted as follows:



71. A racemate (or racemic mixture) is a 50/50 mixture of two enantiomers. A 50/50 mixture of moxifloxacin hydrochloride and the R, R enantiomer is a racemate or a racemic mixture.

72. With respect to Teva’s ANDA No. 77-437, Bayer is asserting infringement of claims 1, 2, 8, 9, and 11 of the ’517 patent. Bayer does not assert infringement of the other claims of the ’517 patent with respect to Teva’s ANDA No. 77-437.

73. With respect to Teva’s ANDA No. 78-073, Bayer is asserting infringement of claims 1, 2, 8, and 11 of the ’517 patent. Bayer does not assert infringement of the other claims of the ’517 patent with respect to Teva’s ANDA No. 78-073.

74. With respect to Teva’s ANDA No. 77-437, Bayer is asserting infringement of claims 1, 2, 3, 4, 5, and 7 of the ’942 patent. Bayer does not assert infringement of the other claims of the ’942 patent with respect to Teva’s ANDA No. 77-437.

75. With respect to Teva's ANDA No. 78-073, Bayer is asserting infringement of claims 1, 2, 3, 4, 5, and 7 of the '942 patent. Bayer does not assert infringement of the other claims of the '942 patent with respect to Teva's ANDA No. 78-073.

76. The '942 patent and '517 patent share a common specification.

77. With respect to Teva's ANDA No. 78-073, Alcon is asserting infringement of claim 1 of the '830 patent. Alcon does not assert infringement of the other claims of the '830 patent with respect to Teva's ANDA No. 78-073.

78. Alcon does not assert infringement of the '830 patent with respect to Teva's ANDA No. 77-437.

# EXHIBIT 2

**EXHIBIT 2**

**PLAINTIFFS' STATEMENT OF ISSUES OF FACT  
THAT REMAIN TO BE LITIGATED**

To the extent that Bayer and Alcon's statement of issues of law contain issues of fact, those issues are incorporated herein by reference. Should the Court determine that any issue identified in this list as an issue of fact is more properly considered an issue of law, Bayer and Alcon incorporate such issues by reference into its statement of issues of law. By including a fact herein, Plaintiffs do not assume the burden of proof or production with regard to that fact. With respect to Teva's allegations that the '942 patent is invalid and unenforceable, and that the '830 patent is invalid, Teva alone bears the burden of proof. Therefore, Bayer and Alcon bear no burden of production or proof unless or until Teva meets its burden of establishing a *prima facie* case of invalidity and/or unenforceability. Only if Teva establishes a *prima facie* case would Bayer and Alcon be required to present rebuttal evidence that the '942 and '830 patents are valid and/or enforceable. If Teva is unable to meet that burden, Bayer and Alcon would have no need to present rebuttal evidence.

During the course of the litigation, Teva asserted numerous defenses in response to Bayer and Alcon's assertions of infringement that Teva has indicated it no longer intends to assert at trial. In particular, Teva asserted that the '517 and '942 patents were invalid for obviousness, lack of enablement and lack of written description. During expert discovery, however, Teva's counsel indicated that Teva no longer intends to pursue these defenses. Teva additionally has clarified that its only basis for asserting that the claims of the '942 patent are invalid for double patenting over the '517 patent is that (a) "the Asserted claims of the '942 patent are from Group IV, the same Group as claims of the '517 patent, and (b) the third sentence of 35 U.S.C. § 121 does not apply." Further, at the close of expert discovery, Teva added three new invalidity

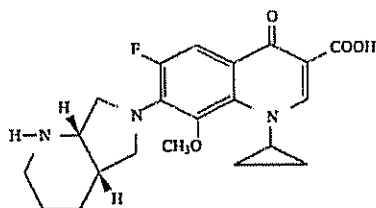
defenses for the '830 patent—failure to satisfy the best mode requirement, lack of written description, and non-enablement.

Bayer and Alcon's identification of the issues of fact that remain to be litigated is based in part on their current understanding of the arguments Teva is likely to make in attempting to support its non-infringement, invalidity, and unenforceability defenses, based upon the pleadings and discovery in the action to date. To the extent Teva attempts to introduce different or additional facts to meet its burden of proof, Plaintiffs reserve the right to object to and/or contest those facts, and to present any and all rebuttal evidence in response to those facts.

## **I. INFRINGEMENT**

In light of the parties' stipulation concerning infringement (D.I. 58), discussed at paragraphs 31-57 of Exhibit 1, the issues of fact remaining with respect to Plaintiffs' infringement case are as follows:

1. Whether the drug products that are the subject of Teva's ANDA Nos. 77-437 and 78-073 (hereinafter "Teva's proposed ANDA products") infringe claim 1 of the '517 patent.
2. Whether Teva's proposed ANDA products infringe claims 1 and 2 of the '942 patent.
3. Whether the drug product that is the subject of Teva's ANDA No. 78-073 contains "moxifloxacin" as used in claim 1 of the '830 patent.
4. Whether the PTO, through granting a Patent Term Extension for the '517 patent, confirmed that moxifloxacin is within the scope of claims 1 and 2 of the '517 patent and claims 1 and 2 of the '942 patent.
5. Whether, as of September 30, 1998, the term "moxifloxacin" was known in the literature and was the International Non-Proprietary Name for the compound with the following structure:



6. Whether Teva has admitted that moxifloxacin is within the scope of claims 1 and 2 of the '517 patent.

7. Whether Teva has admitted that moxifloxacin is within the scope of claims 1 and 2 of the '942 patent.

8. Whether, as of July 15, 1988, there existed a method that could be used to detect the R,R-enantiomer of moxifloxacin.

## **II. DOUBLE PATENTING**

1. Whether Teva has proven by clear and convincing evidence that the asserted claims of the '942 patent are invalid for double patenting.

2. Whether Teva has proven by clear and convincing evidence that the person of ordinary skill in the art as of July 15, 1988 would have selected the species claimed in the '942 patent from the genera of compounds claimed in claims 1 and 2 of the '517 patent.

3. Whether Teva has proven by clear and convincing evidence that the person of ordinary skill in the art as of July 15, 1988 would find the asserted claims of the '942 patent to be obvious in light of claims 4 and 5 of the '517 patent.

4. Whether Teva has proven by clear and convincing evidence that the person of ordinary skill in the art as of July 15, 1988 would have been motivated to modify the compounds claimed in claims 4 and 5 of the '517 patent and, if so, whether such a person would have been motivated to modify the 8-position substituents.



5. Whether Teva has proven by clear and convincing evidence that the person of ordinary skill in the art as of July 15, 1988 would have been motivated to replace the fluorine and chlorine 8-position substituents of the compounds claimed in claims 4 and 5 of the '517 patent with a methoxy substituent.

6. Whether Teva has proven by clear and convincing evidence that, as of July 15, 1988, the art did not teach away from using a methoxy substituent at the 8-position.

7. Whether Teva has proven by clear and convincing evidence that a person of ordinary skill in the art would have had a reasonable expectation of success in modifying the compounds claimed in claim 4 or claim 5 of the '517 patent to practice the claims of the '942 patent.

8. Whether Teva has proven by clear and convincing evidence that the compounds claimed in the '942 patent are structurally similar to compounds 4 and 5 of the '517 patent.

9. Whether the prosecution histories at issue reflect that the Examiner was aware that the claims of the '942 patent were within the scope of the same restriction group as the claims of the '517 patent and found that the claims of the '942 patent met the requirements for patentability.

10. Whether objective indicia of non-obviousness such as unexpected properties, licensing to third parties, satisfaction of a long-felt but unmet need, skepticism in the field, and commercial success demonstrate that the asserted claims of the '942 patent are not invalid for obviousness-type double patenting over the '517 patent.

### **III. INDEFINITENESS**

1. Whether Teva has proven by clear and convincing evidence that claims 1, 3, and 5 of the '942 patent are invalid for indefiniteness because they contain the phrase "substantially free."

2. Whether Teva has proven by clear and convincing evidence that the phrase “substantially free” as used in claims 1, 3, and 5, of the ’942 patent is not capable of construction and is insolubly ambiguous.

3. Whether Teva has proven by clear and convincing evidence that the phrase “substantially free” as used in claims 1, 3, and 5 of the ’942 patent cannot be given any reasonable meaning.

4. Whether Teva has proven by clear and convincing evidence that a person of ordinary skill in the art would not understand what is claimed in claims 1, 3, and 5 of the ’942 patent.

#### **IV. ENFORCEABILITY**

1. Whether Teva has proven by clear and convincing evidence that the ’942 patent is unenforceable due to inequitable conduct.

2. Whether Teva has proven by clear and convincing evidence that an individual with a duty of disclosure withheld material information or made a material misrepresentation during prosecution of United States Patent Application No. 406,448 (“the ’448 application”), the U.S. patent application that ultimately matured into the ’942 patent.

3. Whether Teva has proven by clear and convincing evidence that an individual with a duty of disclosure acted with intent to deceive the PTO.

4. Whether Teva has proven by clear and convincing evidence that the conduct of any individual with a duty of disclosure with respect to the ’448 application is so culpable that the ’942 patent should be unenforceable.

5. Whether Teva has proven by clear and convincing evidence that the statement “Indeed, of all of the fluoroquinolones that we have investigated, the compound of claim 25 is

the best tolerated that we have ever seen” was material, false, knowingly false, and made with specific intent to deceive the PTO.

6. Whether Teva has proven by clear and convincing evidence that the tolerability profile for the betaine of moxifloxacin differs in any material respect from the tolerability of moxifloxacin hydrochloride and was understood to differ in any material respect by any individual with a duty of disclosure to the PTO.

## V. ANTICIPATION

1. Whether Teva has proven by clear and convincing evidence that claim 1 of the '830 patent is anticipated by the '942 patent.

2. Whether Teva has proven by clear and convincing evidence that the '942 patent discloses to a person of ordinary skill in the art of the '830 patent, the invention of claim 1 of the '830 patent, including each and every limitation arranged as in the claim.

3. Whether Teva has proven by clear and convincing evidence that the '942 patent discloses to a person of ordinary skill in the art a “topical ophthalmic composition comprising moxifloxacin.”

4. Whether Teva has proven by clear and convincing evidence that the '942 patent discloses to a person of ordinary skill in the art a topical ophthalmic composition comprising moxifloxacin in the concentration range “0.1 to 1 wt%.”

5. Whether Teva has proven by clear and convincing evidence that the '942 patent discloses to a person of ordinary skill in the art a topical ophthalmic composition comprising moxifloxacin that is sterile, non-irritating, and free of foreign particulates.

6. Whether Teva has proven by clear and convincing evidence that a person of ordinary skill in the art would interpret each and every statement in the '942 patent regarding

“compounds of the invention” to apply to each and every compound of the invention, including moxifloxacin.

7. Whether Teva has proven by clear and convincing evidence that the '942 patent puts a person of ordinary skill in the art in possession of the subject matter of claim 1 of the '830 patent.

8. Whether the '942 patent was before the examiner during prosecution of the '830 patent.

## **VI. OBVIOUSNESS**

1. Whether Teva has proven by clear and convincing evidence that the invention claimed in the '830 patent would have been obvious to the person of ordinary skill in the art as of September 30, 1998 in light of the scope and content of the prior art, the differences between each asserted claim and the prior art, the level of ordinary skill in the art at that time, the properties of the claimed compounds, and objective indicia of nonobviousness.

2. The scope of the relevant field of art regarding claim 1 of the '830 patent as of September 30, 1998.

3. Whether the '830 patent addressed a problem(s) relating to the treatment and prevention of ophthalmic bacterial infections.

4. Whether the '830 patent pertains to the field of treating and preventing ophthalmic bacterial infections.

5. Whether the inventors of the '830 patent have training and experience in the field of the treatment and prevention of ophthalmic bacterial infections.

6. The qualifications and experience of the person of ordinary skill in the art to which the '830 patent is addressed as of September 30, 1998.

7. What the art taught a person of ordinary skill in the art as of September 30, 1998 regarding antibiotics, and in particular, whether a topical ophthalmic formulation containing moxifloxacin would have been considered suitable to meet the needs and requirements in the field for a topical, ophthalmic antibiotic formulation.

8. Whether Teva has proven by clear and convincing evidence that a person of ordinary skill in the art would have had a reason, or been motivated, in light of all of the art as a whole, to select moxifloxacin in the concentrations recited in claim 1 of the '830 patent as an antibiotic with which to make a topical ophthalmic composition.

9. Whether Teva has proven by clear and convincing evidence that the prior art as a whole taught or suggested to a person of ordinary skill in the art the invention claimed in claim 1 of the '830 patent.

10. Whether Teva has proven by clear and convincing evidence that a person of ordinary skill in the art would have expected moxifloxacin to have the same characteristics as other compounds in the fluoroquinolone class of antibiotics, as they relate to use of the compounds in a topical ophthalmic formulation.

11. Whether a person of ordinary skill in the art would have started with or selected the prior art references, and the particular disclosures therein, on which Teva relies in attempting to solve the problems addressed by the '830 patent.

12. Whether a person of ordinary skill in the art would have had a reasonable expectation that the invention claimed in claim 1 of the '830 patent would successfully solve the problems in the field to which the '830 patent is directed.

13. Whether the prior art taught away from the invention recited in claim 1 of the '830 patent.

14. Whether art relied on by Teva for its obviousness defense was before the examiner during prosecution of the '830 patent.

15. Whether objective indicia of non-obviousness such as unexpected desirable properties, commercial success, satisfaction of a long-felt but unmet need, earning praise from practitioners in the field, and skepticism in the field support the validity of claim 1 of the '830 patent.

#### **VII. ENABLEMENT**

1. Whether Teva has proven by clear and convincing evidence that the '830 patent does not enable a person of ordinary skill to make and use the invention of claim 1 of the '830 patent without undue experimentation.

2. Whether the specification of the '830 patent itself describes how to make and use the invention of claim 1 of the '830 patent without undue experimentation.

#### **VIII. BEST MODE**

1. Whether Teva has proven by clear and convincing evidence that the inventors of the '830 patent had a best mode of practicing the invention as recited in claim 1 of the '830 patent as of September 30, 1998.

2. Whether Teva has proven by clear and convincing evidence that the '830 patent does not disclose the best mode of practicing the invention as recited in claim 1 of the '830 patent.

3. Whether Teva has proven by clear and convincing evidence that the best mode was not disclosed in sufficient detail to allow one of skill in the art to practice the best mode without undue experimentation.

**IX. WRITTEN DESCRIPTION**

1. Whether Teva has proven by clear and convincing evidence that the '830 patent does not sufficiently describe to a person of ordinary skill in the art the invention recited in claim 1 of the '830 patent to put a person of ordinary skill in the art in possession of said composition.

2. Whether Teva has proven by clear and convincing evidence that the specification of the '830 patent does not contain an example of a topical ophthalmic composition comprising moxifloxacin without a separate preservative.

3. Whether Teva has proven by clear and convincing evidence that moxifloxacin is not self-preserving.

**X. REQUESTED RELIEF**

1. Whether judgment should be entered providing that the effective date of any FDA approval for Teva commercially to make, use, or sell moxifloxacin or any pharmaceutically utilizable acid addition salt thereof, or any drug product containing moxifloxacin or any pharmaceutically utilizable acid addition salt thereof, including the drug product that is the subject of ANDA No. 77-437, be not earlier than the latest of the expiration dates of the '517 and '942 patents.

2. Whether judgment should be entered providing that the effective date of any FDA approval for Teva commercially to make, use, or sell a topical ophthalmic pharmaceutical composition containing moxifloxacin or any pharmaceutically useful acid addition salt thereof in a concentration of 0.1 to 1.0 wt % and pharmaceutically acceptable vehicle therefor, including the drug product that is the subject of ANDA No. 78-073, be not earlier than the latest of the expiration dates of the '517, '942, and '830 patents.

3. Whether Teva should be enjoined from infringing or inducing the infringement of the '517, '942, and '830 patents.

4. Whether this is an exceptional case pursuant to 35 U.S.C. § 285, because Teva does not have a good-faith basis to believe that it does not infringe a valid and enforceable claim of the '517, '942, and '830 patents.

5. Whether Plaintiffs should be awarded costs.



# EXHIBIT 3

**EXHIBIT 3****TEVA'S STATEMENT OF ISSUES OF FACT THAT REMAIN TO BE LITIGATED**

To the extent that Teva's statement of issues of law contains issues of fact, those issues are incorporated herein by reference. Should the Court determine that any issue identified in this list as an issue of fact is more properly considered an issue of law, Teva incorporates those issues by reference into its statement of issues of law.

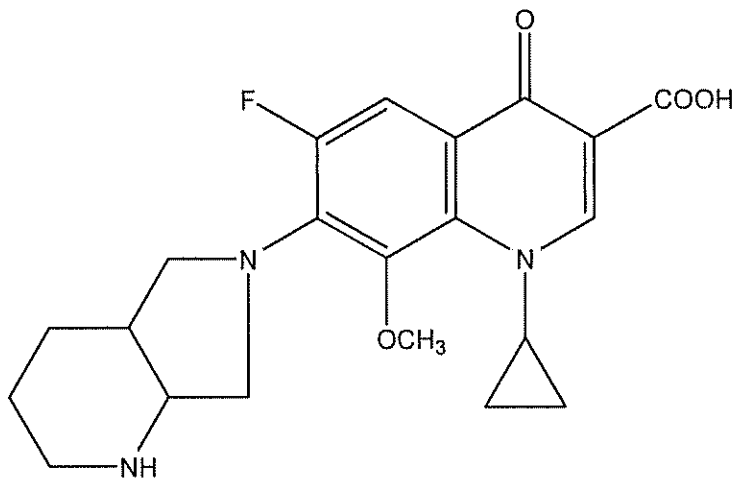
**I. PROSECUTION HISTORIES**

Teva contends that the following facts relate to the proper construction and/or scope of the claims of the '517 and '942 patents-in-issue.

**A. U.S. Patent Application Serial No. 08/406,448 ("The '448 application")**

1. Whether on March 20, 1995 Bayer filed a Preliminary Amendment in U.S. Application No. 08/406,448, canceling all pending claims and adding claims 21-24 as follows:

21. The compound (1-cyclopropyl-7-(2,8-diazabicyclo[4.3.0] non-8-yl)-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid) of the formula



or an addition product thereof with water, an acid or an alkali.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

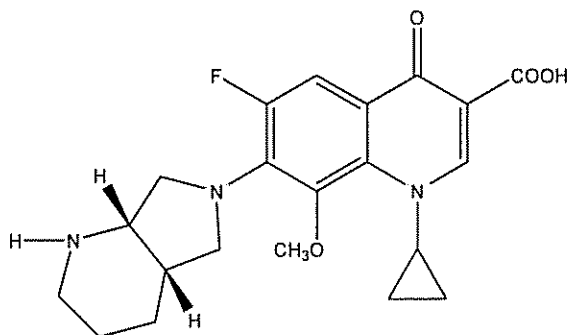
22. An antibacterial composition comprising an antibacterially effective amount of a compound or addition product thereof according to claim 21 and a diluent.
23. A method of combating bacteria in a patient in need thereof which comprises administering to such a patient an antibacterially effective amount of a compound or addition product thereof according to claim 21.
24. A method of promoting the growth of an animal which comprises administering to said animal a growth promoting effective amount of a compound or addition product thereof according to claim 21.

2. Whether claim 21 claims a compound wherein the 6 position is F and the 8 position is OCH<sub>3</sub>, and which, like the claims of the '517 patent, does not specify stereochemistry.

3. Whether in the remarks, applicants stated that "There might be obviousness-type double patenting," but did not point out the restriction requirement in the parent application.

4. Whether applicants (Bayer) filed a Preliminary Amendment on May 19, 1995 adding claims 25-28, as follows:

25. The compound 1-cyclopropyl-7-([S,S]-2,8-diazabicyclo-[4.3.0]non-8-yl)-6-fluoro-1,4-dihydro-8-methoxy-4-oxo-3-quinolinecarboxylic acid having the formula:



or an alkali metal, alkaline earth metal, silver or guanidinium salt thereof or a pharmaceutically

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

utilizable hydrate or acid addition salt thereof, said compound substantially free of other enantiomers and stereoisomers.

26. An antibacterial composition comprising an antibacterially effective amount of a compound or addition product thereof according to claim 25 and a diluent.
27. A method of combating bacteria in a patient in need thereof which comprises administering to such patient an antibacterially effective amount of a compound or addition product thereof according to claim 25.
28. A method of promoting the growth of an animal which comprises administering to said animal a growth promoting effective amount of a compound or addition product thereof according to claim 25.

5. Whether claim 25 is for the S,S-enantiomer, betaine or an alkali metal, alkaline earth metal, silver or guanidinium salt thereof or a pharmaceutically utilizable hydrate or acid addition salt.

6. Whether in the May 19, 1995 Preliminary Amendment filed in U.S. Application No. 08/406,448 applicants argued that new claims 25-28, directed to the S,S enantiomer, were supported by the fourth entry in Table 1 on page 40, and its use, when read in conjunction with the last paragraph on page 39.

7. Whether applicants, in arguing that there is written description support for the enantiomer claimed in claim 25, emphasized that claim 25 is for the single enantiomer only, stating:

“The claimed enantiomer is but one of four theoretically possible diastereomers which correspond to the formula in the table on page 40... Accordingly, the selection of the claimed enantiomer, being of a possible four, would have been immediately envisioned by those skilled in the art...”

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

8. Whether applicants further argued in support of their rationale for including claims 25-28 for the S,S-enantiomer in the '448 application the following:

The clear holding of the Kraatz decision is that the type of disclosure as is involved here, i.e., the apparent disclosure of a stereoisomer mixture, e.g., a racemic mixture, coupled with the teaching that individual isomers can be prepared is anticipatory, being tantamount to express mention of the individual enantiomers either by name or by structural formula. Under these circumstances, it should be clear that the instant claims find clear support in the application just as surely as would be the case had the application mentioned the claimed enantiomer by name or structural formula.

9. Whether the applicants during prosecution of the '448 application represented to the U.S. Patent Office and thus admitted that the structural formula presented in the claims of the '517 patent itself is not for the individual enantiomers because the applicants represented it is necessary to invoke the disclosure preceding Table 1 of the specification in order to demonstrate to the U.S. Patent Office that applicants had "possession" of the individual enantiomers for the '448 application to meet the written description requirement of § 112, ¶ 1.

10. Whether in the Office Action Mailed March 8, 1996 (FH 5607942-000122 to 127), the Examiner rejected claims 21-28:

under the judicially created doctrine of double patenting over claims 1-2 and 8-12 of U.S. Patent No. 4,990,517 since the claims, if allowed, would improperly extend the 'right to exclude' already granted in the patent.

\* \* \* \* \*

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent."

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

11. Whether in the March 8, 1996 Office Action the Examiner rejected claims 21-28 under the judicially created doctrine of double patenting over claims 1-2 and 8-12 of U.S. Patent No. 4,990,517.

12. Whether in support of his rejection, the Examiner relied on the disclosure in the '517 patent including the "fourth compound in Table 1, at cols. 23-24 and the paragraph at col. 24, ll. 17-23," stating "In this case, the subject matter of the claims is fully disclosed in the prior patent."

13. Whether the Examiner also stated "Applicants have pointed to this very disclosure to support a written description of the compounds in claims 21-28; See, e.g., ...."

14. Whether in their June 6, 1996 Amendment, applicants' arguments regarding the Kraatz decisions by the Board (discussed in the preliminary amendment) were necessary to the allowance of claims 25-28 because of applicants' argument that the prior art - the '517 patent - claimed only the racemate of the enantiomers.

15. Whether applicants are estopped from contending that the claim to the racemate depicted in the claims of the '517 patent encompasses the S,S-enantiomer.

16. Whether in an Amendment filed June 10, 1996 applicants argued for the patentability of the claimed invention, stating:

"This application is directed to a single compound of which one enantiomer has especially useful properties."

"The compound is named in the grandparent application (now Patent 4,990,517) but not specifically claimed..."

"Claims 25-28 all require a specific purified enantiomer. This compound has the exact formula depicted in claim 25."

"A compound having this exact formula is not actually depicted either by name or by formula in U.S. - '517."

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

**B. U.S. Patent Application Serial No. 08/026,906**

1. Whether claim 1 of Application No. 08/026,906 as filed depicts five structures, the first of which is a racemate, and the remaining four of which are enantiomers, the claim including the limitation:

“in the form of the racemate or enantiomerically pure form where appropriate.”

2. Whether in claim 15 of the '906 application, which is for a process for the preparation of [a compound] according to claim 1, in which the radical is shown as an enantiomer, it is stated that  $X^2$  (the “B” radical) is “an enantiomerically pure compound of Formula (IV).

3. Whether in an Office Action Mailed September 16, 1993, claims 1-12 were rejected under 35 U.S.C. § 103 as obvious in view of Petersen et al. (the '517 patent).

4. Whether the rejection was based on the Examiner's contention that the '517 patent teaches the racemic forms of the instantly claimed compounds. See formula (I) at col. 1, ll. 15+ (note the  $R^3$  groups; see Table 1 at cols. 23+ and examples 9-15, etc., and the claims. The Examiner then relies on the statement at col. 24, ll. 17-23 that the compounds can be in the form of diastereomers.)

5. Whether the Examiner concluded that instant compounds are “merely the stereoisomers of the known racemates of Petersen.”

6. Whether the Examiner also rejected the claims for double patenting, stating that the instant compounds “are obvious over the racemic compounds already patented.”

7. Whether in response to the Office Action mailed September 16, 1993, applicants filed an amendment on February 16, 1994 in which applicants amended claim 1 to eliminate the racemate and diastereomers and limit the claim to the S,S-enantiomer.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

8. Whether applicants added claim 16 to claim the S,S-enantiomer...

"substantially free of other enantiomers and stereoisomers."

9. Whether the applicants explained the amendment to claim 1 as follows:

"In addition, claim 1 has been amended to limit its scope to the S,S-enantiomerically pure compounds only.

10. Whether in a May 11, 1994 Office Action, the Examiner stated that the application was not entitled to the benefit of the earlier filed cases because the "particular stereoisomeric B group instantly claimed lacks written description support in the parent cases. The disclosure of a genus is not a written description of every embraced species."

11. Whether in a November 8, 1994 Amendment, applicants canceled claims 1-9, 12 and 16, and added new claim 18 for the compound the S,S-enantiomer, including the limitation "said compound substantially free of other enantiomers and stereoisomers," stating that new claim 18 is the same as claim 16, except it adds the structural formula.

12. Whether applicants also explained "The instant claims have been limited to a single species which is supported by the fourth compound in the table at columns 23-24 of the original parent application, which matured into U.S. Patent No. 4,990,517...." (emphasis in original).

13. Whether applicants relied on the fourth compound in Table I in conjunction with the statement that precedes Table I, to support the written description of the S,S-enantiomer.

14. Whether applicants further argued:

It is true that this example [the fourth compound in the table at columns 23-24 of the '517 patent] does not relate expressly to the S,S-enantiomer as is now claimed

\* \* \* \*



## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

Applicants submit that this statement, coupled with the depiction of columns 23-24, constitutes a description of the species now claimed.

...The claims of the patent ['517 patent] embrace mixtures and other individual enantiomers ... they are not the same as the instant claims, which are expressly limited to an S,S-enantiomer "being substantially free of other enantiomers and stereoisomers."

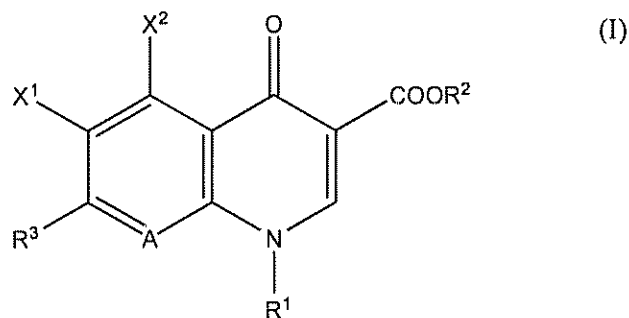
15. Whether in the November 21, 1994 Advisory Action, the Examiner withdrew the 112 written description rejection, but maintained the double-patenting rejection.

## II. U.S. PATENT NO. 4,990,517 ("THE '517 PATENT")

### A. Claim Construction

1. Whether claim 1 of the '517 patent is:

A 7-(pyrrolidinyl)-3-quinolone- or -naphthyridonecarboxylic acid derivative of the formula



in which

$X^1$  represents halogen,

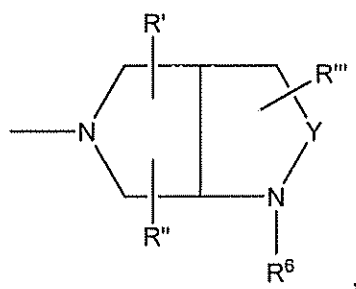
$X^2$  represents hydrogen, amino, alkylamino having 1 to 4 carbon atoms, dialkylamino having 1 to 3 carbon atoms per alkyl group, hydroxyl, alkoxy having 1 to 4 carbon atoms, mercapto, alkylthio having 1 to 4 carbon atoms, arylthio or halogen,

$R^1$  represents alkyl having 1 to 4 carbon atoms, alkenyl having 2 to 4 carbon atoms, cycloalkyl having 3 to 6 carbon atoms, 2-hydroxyethyl, 2-fluoroethyl, methoxy, amino, methylamino, ethylamino, dimethylamino or phenyl which is optionally substituted by 1 or 2 fluorine atoms,

$R^2$  represents hydrogen, alkyl having 1 to 4 carbon atoms or (5-methyl-2-oxo-1,3-dioxol-4-yl)-methyl,

## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

$R^3$  represents a radical of the structure



wherein

$R^6$  represents H, optionally hydroxyl-substituted  $C_1$ - $C_4$ -alkyl, as well as phenyl, benzyl,  $C_1$ - $C_4$ -alkoxycarbonyl,  $C_1$ - $C_4$ -acyl, (5-methyl-2-oxo-1,3-dioxol-4-yl)-methyl, or  $C_3$ - $C_8$ -cycloalkyl,

$R'$  represents H,  $CH_3$  or phenyl,

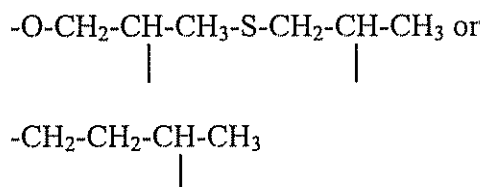
$R''$  represents H,  $CH_3$  or phenyl,

$R'''$  represents H or  $CH_3$ ,

Y represents O,  $CH_2$ ,  $CH_2CH_2$  or  $CH_2-O$ , it being possible for the  $CH_2-O$  group to be linked to the nitrogen either via O or via  $CH_2$ , and

A represents N or  $C-R^8$ , wherein

$R^8$  represents H, halogen, methyl, cyano, nitro, hydroxyl or methoxy or, together with  $R^1$ , forms a bridge having the structure



or an addition product thereof with water, an acid or an alkali.

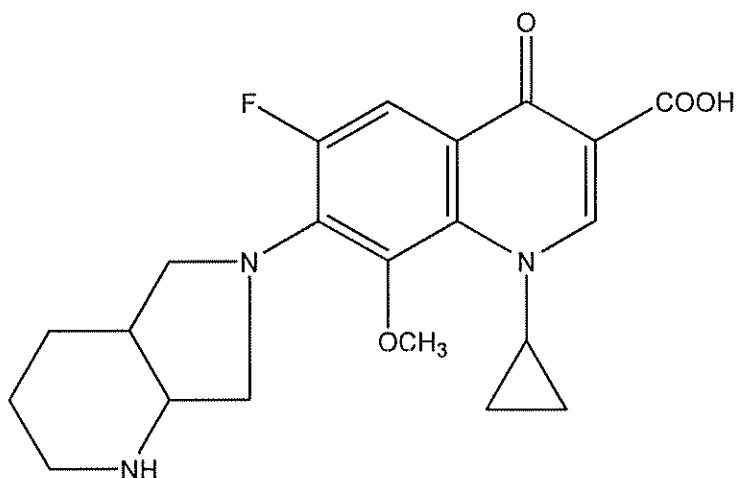
2. Whether diastereomers are stereoisomers that are not enantiomers of one

another.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

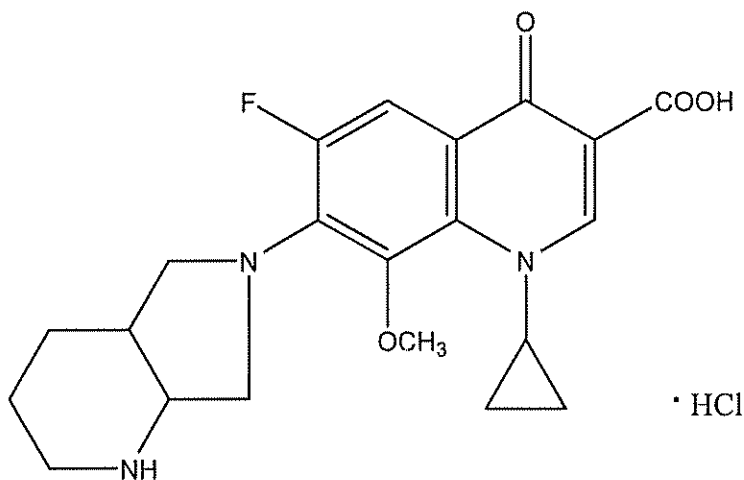
3. Whether the racemate (or racemic mixture) of moxifloxacin<sup>1</sup> is depicted

as:



4. Whether the racemate (or racemic mixture) of moxifloxacin hydrochloride

is depicted as:



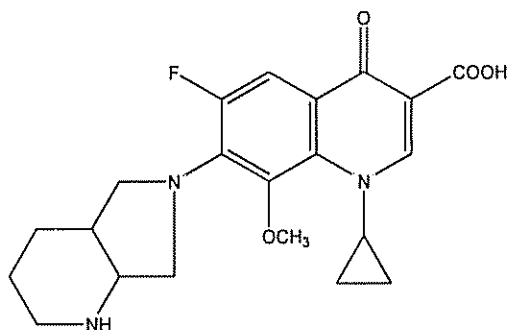
<sup>1</sup> In Teva's Exhibits to the Joint Pretrial Order, the free base of moxifloxacin (S,S) is referred to as "the betaine" and "the S,S-enantiomer" for the issues relating to the '517 and '942 patents.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

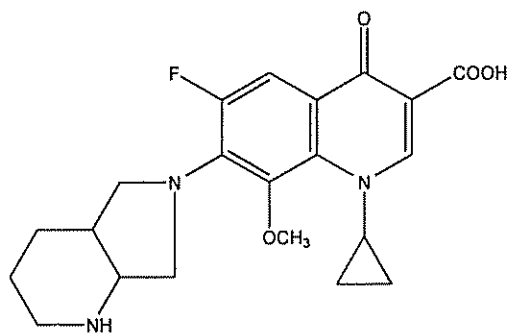
**B. Noninfringement**

1. Whether the active ingredient in the product described in Teva's ANDA No. 78-073 and the product described in Teva's ANDA No. 77-473 is "moxifloxacin hydrochloride."
2. Whether the term "moxifloxacin hydrochloride" in Teva's products means a mixture of the S,S enantiomer and its mirror image, the R,R enantiomer, but not as a racemate.
3. Whether the "moxifloxacin hydrochloride" in Teva's products is not a diastereomeric mixture in which there are two or more diastereomers.
4. Whether the "moxifloxacin hydrochloride" in Teva's products is not enantiomerically pure.
5. Whether Plaintiffs have not tested any product described in either of Teva's ANDA No. 77-437 or ANDA No. 78-073.
6. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 77-437 is a mixture of the S,S and R,R enantiomers of moxifloxacin hydrochloride other than as a racemate.
7. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 78-073 is a mixture of the S,S and R,R enantiomers of moxifloxacin hydrochloride other than as a racemate.
8. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 77-437 does not infringe claims 1, 2, 8, 9, and 11 of the '517 patent because it does not contain a racemate or diastereomeric mixture of compounds having the following atomic arrangement:

## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated



9. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 78-073 does not infringe claims 1, 2, 8, 9, and 11 of the '517 patent because it does not contain a racemate or diastereomeric mixture of compounds having the following atomic arrangement:



### III. U.S. PATENT NO. 5,607,942 ("THE '942 PATENT")

#### A. Claim Construction

1. Whether claim 1 of the '942 patent is:

The compound 1-cyclopropyl-7-([S,S]-2,8-diazabicyclo-[4.3.0]non-8-yl)-6-fluoro-1,4-dihydro-8-methoxy-4-oxo-3-quinolinecarboxylic acid having the formula:

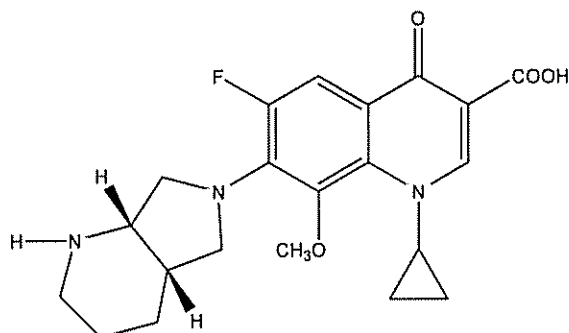
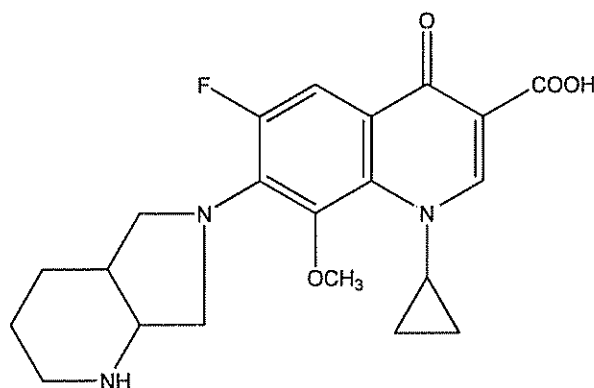


Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

or an alkali metal, alkaline earth metal, silver or guanidinium salt thereof or a pharmaceutically utilizable hydrate or acid addition salt thereof, said compound substantially free of other enantiomers and stereoisomers.

2. Whether claim 2 of the '942 patent is:

The compound (1-cyclopropyl-7-(S,8-diazabicyclo[4.3.0]non-8-yl-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3-quinolonecarboxylic acid) of the formula



or an addition product thereof with water, an acid or an alkali.

**B. Noninfringement**

1. Whether the active ingredient in the product described in Teva's ANDA No. 78-073 and the product described in Teva's ANDA No. 77-473 is "moxifloxacin hydrochloride."

2. Whether the term "moxifloxacin hydrochloride" in Teva's products means a mixture of the S,S enantiomer and its mirror image, the R,R enantiomer, but not as a racemate.

3. Whether the "moxifloxacin hydrochloride" in Teva's products is not a diastereomeric mixture in which there are two or more diastereomers.

4. Whether the "moxifloxacin hydrochloride" in Teva's product is not enantiomerically pure.

5. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 77-437 is not "substantially free of other enantiomers and stereoisomers" of

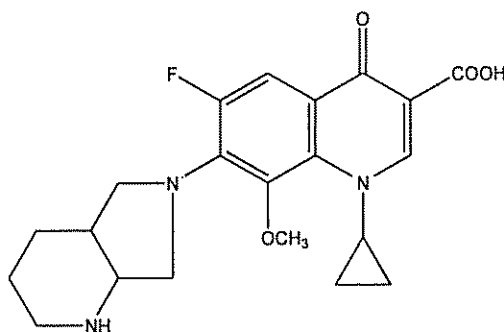
## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

moxifloxacin hydrochloride because that product contains a detectable amount of the R,R enantiomer of moxifloxacin hydrochloride.

6. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 77-437 does not infringe claims 1, 3 or 5 of the '942 patent because it is not "substantially free of other enantiomers and stereoisomers" of moxifloxacin hydrochloride because that product contains a detectable amount of the R,R isomer of moxifloxacin hydrochloride.

7. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 77-437 is a mixture of the S,S and R,R enantiomers of moxifloxacin hydrochloride other than as a racemate.

8. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 77-437 does not infringe claims 2, 4 or 7 of the '942 patent because it does not contain a racemate or diastereomeric mixture of compounds having the following atomic arrangement:



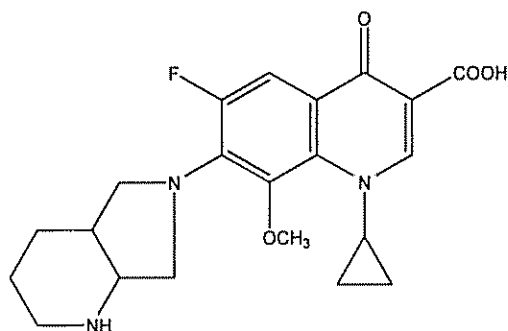
9. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 78-073 is not "substantially free of other enantiomers and stereoisomers" of moxifloxacin hydrochloride because that product contains a detectable amount of the R,R enantiomer of moxifloxacin hydrochloride.

## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

10. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 78-073 does not infringe claims 1, 3 or 5 of the '942 patent because it is not "substantially free of other enantiomers and stereoisomers" of moxifloxacin hydrochloride because that product contains a detectable amount of the R,R isomer of moxifloxacin hydrochloride.

11. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 78-073 is a mixture of the S,S and R,R enantiomers of moxifloxacin hydrochloride other than as a racemate.

12. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 78-073 does not infringe claims 2, 4 or 7 of the '942 patent because it does not contain a racemate or diastereomeric mixture of compounds having the following atomic arrangement:



13. Whether Plaintiffs are estopped from contending that an active pharmaceutical ingredient containing the R,R enantiomer infringes any claim of the '942 patent under the doctrine of equivalents.

### C. Indefiniteness

1. Whether the '942 patent provides no indication as to what the term "substantially free of other enantiomers and stereoisomers" means.



Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

2. Whether the term "substantially free of other enantiomers and stereoisomers" does not have an accepted definition used by those skilled in the relevant art.

3. Whether the term "substantially free of other enantiomers and stereoisomers" as used in the claims of the '942 patent is insolubly ambiguous.

4. Whether the definition of "substantially free" in the context of the claims of the '942 patent, as offered by Plaintiffs, i.e. "largely, but not necessarily, free," of other enantiomers and stereoisomers, is also insolubly ambiguous.

**D. Double Patenting**

**i. The Restriction Requirement In The '942 Patent's Parent Application**

1. Whether Bayer filed U.S. Patent Application Serial No. 07/375,434 ("the '434 application") for "7-(1-pyrrolidinyl)-3-Quinolone- and -Naphthyridonecarboxylic Acid Derivatives As Antibacterial Agents and Feed Additives," on June 30, 1989.

2. Whether the '434 application was filed with 20 claims.

3. Whether on or about April 4, 1990, during the prosecution of the '434 application, the Patent Office Examiner imposed a restriction requirement on or about April 4, 1990.

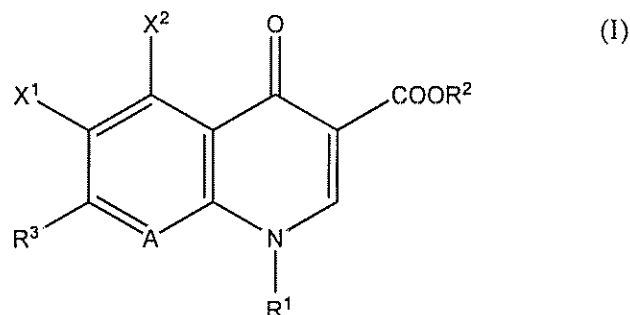
4. Whether, in this restriction requirement, the Examiner identified nine claim groups and requested that Bayer elect one of the groups for prosecution.

5. Whether the '434 application, as filed, contained 3 independent claims, namely, claims 1, 19, and 20.

6. Whether claim 1, as filed in the '434 application, read:

A 7-(pyrrolidinyl)-3-quinolone- or -naphthyridonecarboxylic acid derivative of the formula

## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated



in which

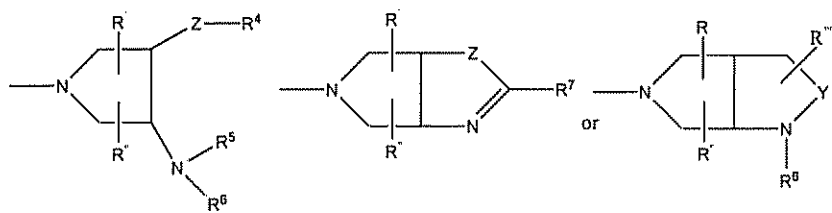
$X^1$  represents halogen,

$X^2$  represents hydrogen, amino, alkylamino having 1 to 4 carbon atoms, dialkylamino having 1 to 3 carbon atoms per alkyl group, hydroxyl, alkoxy having 1 to 4 carbon atoms, mercapto, alkylthio having 1 to 4 carbon atoms, arylthio or halogen,

$R^1$  represents alkyl having 1 to 4 carbon atoms, alkenyl having 2 to 4 carbon atoms, cycloalkyl having 3 to 6 carbon atoms, 2-hydroxyethyl, 2-fluoroethyl, methoxy, amino, methylamino, ethylamino, dimethylamino or phenyl which is optionally substituted by 1 or 2 fluorine atoms,

$R^2$  represents hydrogen, alkyl having 1 to 4 carbon atoms or (5-methyl-2-oxo-1,3-dioxol-4-yl)-methyl,

$R^3$  represents a radical of the structure



wherein

$R^4$  represents H,  $C_1$ - $C_4$ , aryl or  $C_1$ - $C_4$ -acyl,

$R^5$  represents H,  $C_1$ - $C_4$ -alkyl,  $\text{NH}$  or  $\text{OCH}_3$ , it also being possible for  $R^4$  and  $R^5$  together to denote a  $C_1$ - $C_4$ -alkylene bridge which is optionally mono- or disubstituted by methyl,

$R^6$  represents H, optionally hydroxyl-substituted  $C_1$ - $C_4$ -alkyl, as well as aryl, heteroaryl, benzyl,  $C_1$ - $C_4$ -alkoxycarbonyl,  $C_1$ - $C_4$ -acyl, (5-methyl-2-oxo-1,3-dioxol-4-yl)-methyl, or  $C_3$ - $C_8$ -cycloalkyl,

## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

$R^7$  represents H or  $C_1$ - $C_4$ -alkyl,

$R^*$  represents H,  $CH_3$  or phenyl,

$R''$  represents H,  $CH_3$  or phenyl,

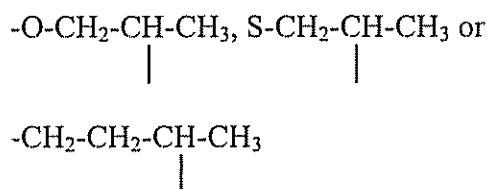
$R'''$  represents H or  $CH_3$ ,

Y represents O,  $CH_2$ ,  $CH_2CH_2$  or  $CH_2-O$ , it being possible for the  $CH_2-O$  group to be linked to the nitrogen either via O or via  $CH_2$ , and

Z represents O or S, and

A represents N or  $C-R^8$ , and

$R^8$  represents H, halogen, methyl, cyano, nitro, hydroxyl or methoxy or, together with  $R^1$ , forms a bridge having the structure



or an addition product thereof with water, an acid or an alkali.

7. Whether claim 19, as filed in the '434 application, read:

A compound selected from the group consisting of

2-oxa-5,8-diazabicyclo[4.3.0]nonane dihydrochloride,

trans-2-oxa-5,8-diazabicyclo[4.3.0]nonane,

5-methyl-2-oxa-5,8-diazabicyclo[4.3.0]nonane dihydrochloride,

2,8-diazabicyclo[4.3.0]nonane,

4-methyl-2,8-diazabicyclo[4.3.0]nonane,

2-methyl-2,8-diazabicyclo[4.3.0]nonane,

2,7-diazabicyclo[3.3.0]octane,

3-oxa-2,7-diazabicyclo[3.3.0]octane,

2-methyl-3-oxa-2,7-diazabicyclo[3.3.0]octane,

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

2,5-dimethyl-3-oxa-2,7-diazabicyclo[3.3.0]octane,

2,8-dimethyl-3-oxa-2,7-diazabicyclo[3.3.0]octane,

2-methyl-4-oxa-2,8-diazabicyclo[4.3.0]nonane,

3-methyl-2,7-diazabicyclo[3.3.0]octane,

2,3-dimethyl-2,7-diazabicyclo[3.3.0]octane,

ethyl 2,7-diazabicyclo[3.3.0]octane-2-carboxylate,

2-phenyl-2,7-diazabicyclo[3.3.0]octane,

4-oxa-2,8-diazabicyclo[4.3.0]nonane,

trans-3-ethylamino-4-methylthio-pyrrolidine and

trans-3-methylamino-4-methylthio-pyrrolidine.

8. Whether claim 20, as filed in the '434 application, read:

A compound selected from the group consisting of

5,6,7,8-tetrafluoro-1-(2,4-difluorophenyl)-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid,

5,7-dichloro-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid and

5,7-dichloro-6-fluoro-1-(2,4-difluorophenyl)-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid.

9. Whether during the prosecution of the '434 application the Examiner

entered a requirement for restriction between the following groups:

- I. Claims 1-5, 11 and 12-28, drawn to cpds. wherein A R<sup>4</sup> and R<sup>5</sup> do not form an alkylene bridge, classified in Class 544, subclass 48 e.g..
- II. Claims 1-3, 6 and 12-18, drawn to cpds. wherein A, R<sup>4</sup> and R<sup>5</sup> form an alkylene bridge, classified in Class 544, subclass 48 e.g..
- III. Claims 1-3 and 12-16, drawn to cpds. wherein R<sup>3</sup> is a moiety B, classified in Class 546, subclass 123 e.g.

## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

- IV. Claims 1-3, 7-10 and 12-18, drawn to cpds. wherein  $R^3$  is a moiety C, classified in Class 546, subclass 113 e.g..

Intermediate claim 19 is divided into 4 gps. below. There are 20 separate cpds. named in said claim. They are numbered in descending order and will be denoted by the appropriate number.

- V. Claim 19, drawn to 2-oxa,5,8-diaza-bycyclo[4.3.0] nonanes, i.e. cpds. 1-3, classified in Class 544, subclass 105.
- VI. Claim 19, drawn to 2,8-diazabycyclo[4.3.0] nonanes and 2,7-diazabicyclo[3.3.0] octanes, i.e. cpds. 4-8 and 14-17, classified in Class 548, subclass 453 e.g..
- VII. Claim 19, drawn to 3-oxa-2,7-diaza-bicyclo [3.3.0] octanes and 4-oxa-2,8-diazabicyclo [4.3.0] nonanes, i.e., cpds. 9-13 and 18, classified in Class 544, subclass 91 e.g..
- VIII. Claim 19, drawn to 3-alkyamino-4-methylthiopyrrolidines i.e. cpds. 19 and 20, classified in Class 548, subclass 519.
- IX. Claim 20, drawn to 7-fluoro or chloro 1,4-dihydro-4-oxo-quinolone carboxylic acids which are intermediates, classified in Class 546, subclass 156.

10. Whether with respect to Restriction Groups V-IX the Examiner did not require restriction based on stereochemistry even when stereochemistry was indicated for some compounds within the claims.

11. Whether Restriction Group IV did not require restriction between any of the enantiomers or diastereomers of the  $R^3$  moiety.

12. Whether Restriction Group IV did not require an election of any specific enantiomer.

13. Whether Restriction Group IV did not require an election between any of the individual members of substituent group A.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

14. Whether there was no requirement for restriction between a compound and an antibacterial composition comprising a compound.

15. Whether there was no requirement for restriction between a compound and a method for treating a patient comprising administering a composition comprising a compound.

16. Whether Restriction Group IV is by the U.S. Patent Office in class/subclass 546/113.

17. Whether Restriction Group IV is the only Restriction Group classified by the U.S. Patent Office in class/subclass 546/113.

18. Whether Bayer subsequently filed U.S. Application Serial No. 08/406,448 ("the '448 application") as a divisional application claiming priority to the '434 application. The '448 application issued as U.S. Patent No. 5,607,942 ("the '942 patent").

19. Whether the '942 patent itself shows that the '942 patent is classified in class/subclass 546/200 and class/subclass 546/113.

20. Whether U.S. Patent Application Serial No. 07/580,906 is a divisional application claiming priority to the '434 application.

21. Whether U.S. Patent Application Serial No. 07/580,906 issued as U.S. Patent 5,059,597 ("the '597 patent").

22. Whether the '597 patent itself shows that the '597 patent is not classified in either class/subclass 546/113 or class/subclass 546/200.

23. Whether U.S. Patent Application Serial No. 07/737,631 is a divisional application claiming priority to the '434 application.

24. Whether U.S. Patent Application Serial No. 07/737,631 issued as U.S. Patent 5,416,096 ("the '096 patent").

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

25. Whether the '096 patent itself shows the '096 patent is not classified in either class/subclass 546/113 or class/subclass 546/200.

26. Whether U.S. Patent Application Serial No. 08/026,906 ("the '906 application") is a now-abandoned divisional application claiming priority to the '434 application.

27. Whether on or about September 13, 1993, the Examiner entered a requirement for restriction in the '906 application between the following groups:

- I. Claims 1-12, drawn to compounds, compositions and method (sic) of treatment, classified in Class 544, subclass (sic) 101, 105; Class 514, subclasses 230.2, 230.5, 300.
- II. Claim 13, drawn to a process for preparing compounds of Group I by reacting formula (II) with formula (III), classified in Class 544, subclass 101.
- III. Claim 14, drawn to a process for preparing compounds of Group I by reacting formula (II) with formula (IV), classified in Class 544, subclass 101.
- IV. Claim 15, drawn to a process for preparing compounds of Group I by reacting formula (V) with formula (VI).

28. Whether the requirement for restriction entered in the '906 did not require restriction between the racemate and any stereoisomers.

29. Whether none of the restriction groups in the requirement for restriction entered in the '906 application were identified by the Examiner as being in either class/subclass 546/113 or class/subclass 546/200.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

30. Whether none of the Restriction Groups in the '906 application were based on stereochemistry.

31. Whether Restriction Group IV in the '434 application was restricted to claims drawn to compounds within the scope of claim 1 of the '434 application, as filed, wherein  $R^3$  is moiety C.

32. Whether by the presentation of the Markush group defining the substituent  $R^8$  the applicants of the '434 application made a representation that for the purpose of the claimed invention the members of the group (i.e., "H, halogen, ... or methoxy or...") are equivalents.

33. Whether the Examiner did not require restriction between any of the members of the  $R^8$  Markush group.

34. Whether the Examiner did not require an election of the species of any of the members of the  $R^8$  Markush group.

35. Whether a compound within the scope of claim 1 of the '434 application having any of the members of the Markush group, including a halogen or a methoxy substituent, at position 8 of the quinolone core is within restriction Group IV so long as the compound also had moiety C at the  $R^3$  position.

36. Whether, the Patent Office Examiner thus determined that a compound within the scope of claim 1 having moiety C at the  $R^3$  position and a halogen at position 8 of the quinolone core is not patentably distinct from a compound within the scope of claim 1 having moiety C at the  $R^3$  position and a *different halogen or methoxy* at position 8 of the quinolone core



## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

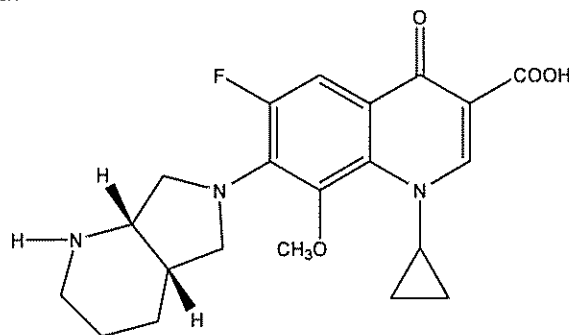
37. Whether, in response to the restriction requirement, Bayer elected the claims of Group IV, and U.S. Patent No. 4,990,517 ("the '517 patent") issued with claims from Group IV of the restriction requirement.

38. Whether the claims of the '517 patent are within restriction Group IV.

**ii. Claims 1, 3, And 5 Of The '942 Patent**

1. Whether claim 1 of the '942 patent is:

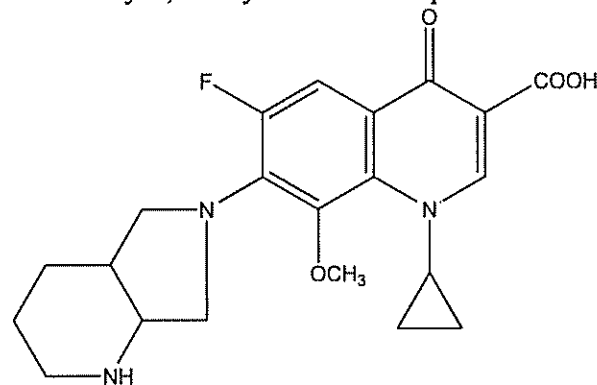
The compound 1-cyclopropyl-7-([S,S]-2,8-diazabicyclo-[4.3.0]non-8-yl)-6-fluoro-1,4-dihydro-8-methoxy-4-oxo-3-quinolinecarboxylic acid having the formula:



or an alkali metal, alkaline earth metal, silver or guanidinium salt thereof or a pharmaceutically utilizable hydrate or acid addition salt thereof, said compound substantially free of other enantiomers and stereoisomers.

2. Whether claim 2 of the '942 patent is:

The compound (1-cyclopropyl-7-(S,8-diazabicyclo[4.3.0]non-8-yl)-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3-quinolonecarboxylic acid) of the formula



or an addition product thereof with water, an acid or an alkali.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

3. Whether the structures shown in claims 1 and 2 of the '942 patent are within the scope of Restriction Group IV entered during the prosecution of the '434 application as filed.

4. Whether the structures shown in claims 1 and 2 of the '942 patent are not within the scope of Restriction Groups I-III, V-IX entered during the prosecution of the '434 application.

5. Whether the only Restriction Group from the '434 application which could include claim 1 and/or claim 2 of the '942 patent is Restriction Group IV.

6. Whether during prosecution of the '942 patent the Examiner never imposed a requirement for restriction between the claims which ultimately issued as claims 1 and 2 of the '942 patent.

7. Whether claims 1, 3, and 5 of the '942 patent are not consonant with the restriction requirement entered in the '434 application.

8. Whether because claims 1, 3, and 5 of the '942 patent are not consonant with the restriction requirement entered in the '434 application, the third sentence of 35 U.S.C. § 121 does not apply to the '942 patent.

9. Whether because claims 1, 3, and 5 of the '942 patent are not consonant with the restriction requirement entered in the '434 application, those claims are not patentably distinct from the claims of the '517 patent.

10. Whether because claims 1, 3, and 5 of the '942 patent are not consonant with the restriction requirement, they are invalid for double patenting.

11. Whether claims 2, 4 and 7 of the '942 patent are not consonant with the restriction requirement entered in the '434 application.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

12. Whether because claims 2, 4, and 7 of the '942 patent are not consonant with the restriction requirement entered in the '434 application, the third sentence of 35 U.S.C. § 121 does not apply to the '942 patent.

13. Whether because claims 2, 4, and 7 of the '942 patent are not consonant with the restriction requirement entered in the '434 application, those claims are not patentably distinct from the claims of the '517 patent.

14. Whether because claims 2, 4, and 7 of the '942 patent are not consonant with the restriction requirement, they are invalid for double patenting.

15. Whether a terminal disclaimer has not been filed for the '942 patent.

16. Whether objective indicia of nonobviousness are not relevant to the double-patenting inquiry.

**E. Inequitable Conduct**

**i. Dr. Klaus-Dieter Bremm**

1. Whether on March 20, 1995 U.S. Patent Application 08/406,448 ("the '448 application") was filed in the name of Uwe Petersen et al.

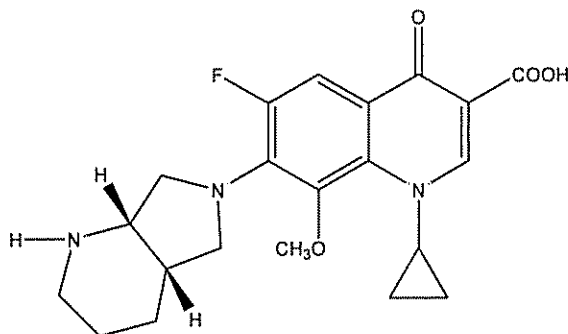
2. Whether as of July 20, 1995, the '448 application had not been examined by the United States Patent and Trademark Office ("Patent Office").

3. Whether the applicants submitted preliminary amendments in order to obviate an expected obviousness-type double patenting rejection made in connection with U.S. Patent Application 08/026,906.

4. Whether as of July 20, 1995, claim 25 of the '448 application recited as follows:

## Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

The compound 1-cyclopropyl-7-([S,S]-2,8-diazabicyclo-[4.3.0]non-8-yl)-6-fluoro-1,4-dihydro-8-methoxy-4-oxo-3-quinolinecarboxylic acid having the formula:



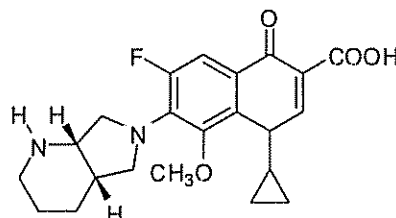
or an alkali metal, alkaline earth metal, silver or guanidinium salt thereof or a pharmaceutically utilizable hydrate or acid addition salt thereof, said compound substantially free of other enantiomers and stereoisomers.

5. Whether on July 20, 1995, Dr. Klaus-Dieter Bremm ("Dr. Bremm") executed a declaration ("the Bremm declaration") in conjunction with the prosecution of U.S. Patent Application Serial No. 08/406,448 ("the '448 application").
6. Whether the Bremm declaration was filed in the Patent Office on or about September 21, 1995, with a third preliminary amendment, in connection with the '448 application.
7. Whether Dr. Bremm consulted with Dr. Uwe Petersen in drafting the declaration.
8. Whether Dr. Bremm drafted all sections of the Bremm declaration other than paragraph 6.
9. Whether Dr. Bremm intended the Bremm declaration to respond to questions raised by the Patent Office in connection with the examination of the '448 application.
10. Whether the Bremm declaration states: "of all the fluoroquinolones that we have investigated, the compound of claim 25 is the best tolerated that we have seen."

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

11. Whether, as of July 20, 1995, Dr. Bremm knew that a compound referred to as Bay Y 6957 had been investigated at Bayer.

12. Whether, as of July 20, 1995, Dr. Bremm knew that the chemical structure of Bay Y 6957 to be:



13. Whether Bay Y 6957 is a compound within the scope of claim 25, one of the claims pending in the '448 application as of July 20, 1995.

14. Whether, in June 1993, Dr. Bremm participated in a meeting at Bayer during which the results of investigations of Bay Y 6957 were discussed.

15. Whether Dr. Bremm received a copy of the minutes of this meeting.

16. Whether the minutes of this meeting indicate that the result of "intensified investigation" showed that Bay Y 6957 showed "surprisingly poor tolerability" in test animals.

17. Whether, as of July 20, 1995, Dr. Bremm knew that Bay Y 6957 was not recommended as a candidate for clinical development because of its "surprisingly poor tolerability" in test animals.

18. Whether, as of July 20, 1995, Dr. Bremm knew that salts of Bay Y 6957 (which is a betaine or switterion) were better tolerated than Bay Y 6957.

19. Whether, as of July 20, 1995, Dr. Bremm knew that the hydrochloride salt of Bay Y 6957 (i.e., Bay 12-8039) was better tolerated than Bay Y 6957.

20. Whether Dr. Bremm intended the Bremm declaration to inform the Patent Office of the superior tolerability of only the hydrochloride salt (Bay 12-8039).

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

21. Whether Dr. Bremm did not inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957.

22. Whether Dr. Bremm intended not to inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957.

23. Whether the "surprisingly poor tolerability" of Bay Y 6957 was material to the patentability of the '448 application.

24. Whether Dr. Bremm did not inform the Patent Office of the results of the investigations of Bay Y 6957.

25. Whether Dr. Bremm intended not to inform the Patent Office of the results of investigations of Bay Y 6957.

26. Whether the results of the investigations of Bay Y 6957 were material to the patentability of the '448 application.

27. Whether by not disclosing the "surprisingly poor tolerability" of Bay Y 6957, the Bremm declaration misrepresented the superior tolerability of "the compound of claim 25" based only on data for the hydrochloride salt of Bay Y 6957 (Bay 12-8039).

28. Whether according to an Examiner Interview Summary Record for an interview on July 1, 1996, the Examiner at the Patent Office agreed that the "showing of unexpected results overcomes the obviousness-type rejection."

29. Whether on July 18, 1996, the Examiner at the Patent Office issued a Notice of Allowance for the '448 application.

30. Whether the '448 application issued as U.S. Patent 5,607,942 on March 4, 1997.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

31. Whether Dr. Bremm's intentional failure to inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957 breached his duties under 37 C.F.R. § 1.56.

32. Whether Dr. Bremm's intentional failure to inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957 amounted to inequitable conduct.

33. Whether Dr. Bremm's intentional failure to inform the Patent Office of the results of investigations of Bay Y 6957 breached his duties under 37 C.F.R. § 1.56.

34. Whether Dr. Bremm's intentional failure to inform the Patent Office of the results of investigations of Bay Y 6957 amounted to inequitable conduct.

35. Whether Dr. Bremm's intentional misrepresentation of the superior tolerability of "the compound of claim 25" based only on data for the hydrochloride salt of Bay Y 6957 (i.e., Bay 12-8039), while not disclosing that the Bay Y 6957 compound was poorly tolerated, breached his duties under 37 C.F.R. § 1.56.

36. Whether Dr. Bremm's intentional misrepresentation of the superior tolerability of "the compound of claim 25" based only on data for the hydrochloride salt of Bay Y 6957 (i.e., Bay 12-8039), while not disclosing that the Bay Y 6957 compound was poorly tolerated, amounted to inequitable conduct.

37. Whether the '942 patent is unenforceable due to the inequitable conduct of Dr. Klaus-Dieter Bremm.

**ii. Dr. Uwe Petersen**

1. Whether Dr. Bremm was asked by Dr. Uwe Petersen, the first named inventor of the '448 application, to provide the Patent Office with additional information on some of the compounds of the '448 application.

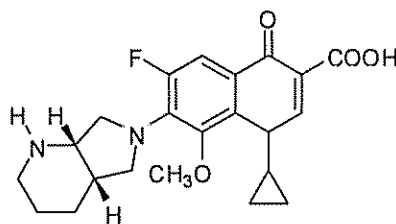
Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

2. Whether Dr. Petersen intended the Bremm declaration to respond to questions raised by the Patent Office in connection with the examination of the '448 application.

3. Whether Dr. Petersen assisted Dr. Bremm in drafting the language in the Bremm declaration stating "of all the fluoroquinolones that we have investigated, the compound of claim 25 is the best tolerated that we have ever seen."

4. Whether, as of July 20, 1995, Dr. Petersen knew that a compound referred to as Bay Y 6957 had been investigated by Bayer.

5. Whether, as of July 20, 1995, Dr. Petersen knew the chemical structure of Bay Y 6957 to be:



6. Whether, as of July 20, 1995, Dr. Petersen knew that Bay Y 6957 is a compound within the scope of claim 25, one of the claims pending then in the '448 application.

7. Whether, in June 1993, Dr. Petersen participated in a meeting at Bayer, during which the results of investigations of Bay Y 6957 were discussed.

8. Whether Dr. Petersen received a copy of the minutes of this meeting.

9. Whether these minutes indicate that the result of "intensified investigation" showed that Bay Y 6957 showed "surprisingly poor tolerability" in test animals.

10. Whether, as of July 20, 1995, Dr. Petersen knew that Bay Y 6957 was not recommended as a candidate for clinical development because of its "surprisingly poor tolerability" in test animals.



Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

11. Whether, as of July 20, 1995, Dr. Petersen knew that Bay Y 6957 was not recommended as a candidate for clinical development because it was lethal when administered to test animals.

12. Whether Dr. Petersen knew that the Bremm declaration did not inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957.

13. Whether Dr. Petersen intended not to inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957.

14. Whether Dr. Petersen intended for the Bremm declaration not to inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957.

15. Whether the "surprisingly poor tolerability" of Bay Y 6957 was material to the patentability of the '448 application.

16. Whether Dr. Petersen knew that the Bremm declaration did not inform the Patent Office that Bay Y 6957 was lethal when administered to test animals.

17. Whether Dr. Petersen intended not to inform the Patent Office that Bay Y 6957 was lethal when administered to test animals.

18. Whether Dr. Petersen intended for the Bremm declaration not to inform the Patent Office that Bay Y 6957 was lethal when administered to test animals.

19. Whether Bay Y 6957 was lethal when administered to test animals was material to the patentability of the '448 application.

20. Whether Dr. Petersen intended not to inform the Patent Office of the results of investigations of Bay Y 6957.

21. Whether Dr. Petersen intended for the Bremm declaration not to inform the Patent Office of the results of investigations of Bay Y 6957.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

22. Whether the results of investigations of Bay Y 6957 were material to the patentability of the '448 application.

23. Whether, according to an Examiner Interview Summary Record for an interview on July 1, 1996, the Examiner at the Patent Office agreed that the "showing of unexpected results overcomes the obviousness-type rejection."

24. Whether on July 18, 1996, the Examiner at the Patent Office issued a Notice of Allowance for the '448 application.

25. Whether the '448 application issued as U.S. Patent 5,607,942 on March 4, 1997.

26. Whether Dr. Petersen's intentional failure to inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957 breached his duties under 37 C.F.R. § 1.56.

27. Whether Dr. Petersen's intentional failure to inform the Patent Office of the "surprisingly poor tolerability" of Bay Y 6957 amounted to inequitable conduct.

28. Whether Dr. Petersen's intentional failure to inform the Patent Office that Bay Y 6957 was lethal when administered to test animals breached his duties under 37 C.F.R. § 1.56.

29. Whether Dr. Petersen's intentional failure to inform the Patent Office that Bay Y 6957 was lethal when administered to test animals amounted to inequitable conduct.

30. Whether Dr. Petersen's intentional failure to inform the Patent Office of the results of investigations of Bay Y 6957 breached his duties under 37 C.F.R. § 1.56.

31. Whether Dr. Petersen's intentional failure to inform the Patent Office of the results of investigations of Bay Y 6957 amounted to inequitable conduct.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

32. Whether the '942 patent is unenforceable due to the inequitable conduct of Dr. Uwe Petersen.

**IV. U.S. PATENT NO. 6,716,830 ("THE '830 PATENT")**

**A. Claim Construction**

1. Whether claim 1 of the '830 patent is

A topical ophthalmic pharmaceutical composition comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt % and pharmaceutically acceptable vehicle therefor.

2. Whether the '830 patent states, at column 1, lines 13-21, that "The present invention is directed to the provision of topical antibiotic pharmaceutical compositions for the treatment of ophthalmic, otic and nasal infections, particularly bacterial infections, and to methods of treating ophthalmic, otic and nasal infections by applying those compositions to the affected tissues. The compositions and methods of the invention are based on the use of a new class of antibiotics. The compositions of the present invention may also contain one or more anti-inflammatory agents."

3. Whether the '830 patent states, at column 2, lines 5-9, that: "The invention is based on the use of a potent new class of antibiotics to treat ophthalmic, otic or nasal tissues."

4. Whether the '830 patent states, at column 2, line 49 through column 3, line 35, that: "The antibiotics used in the compositions and methods of the present invention have the following formula (I):

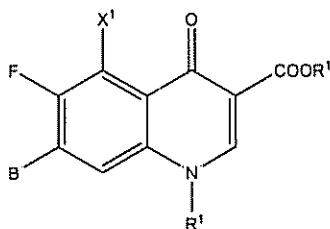
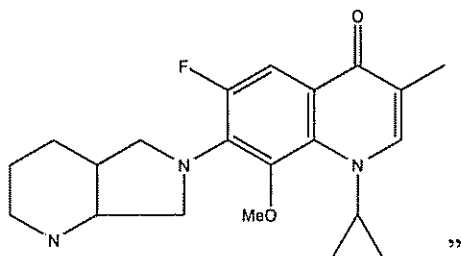


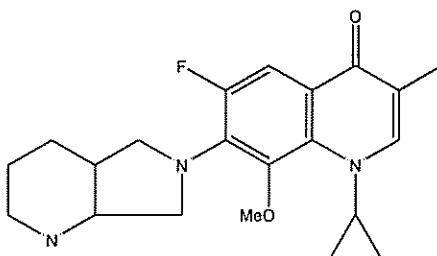
Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

wherein: . . .”

5. Whether the '830 patent states, at column 3, lines 36-48, that: “The compound Moxifloxacin is most preferred. Moxifloxacin has the following structure:



6. Whether Alcon never synthesized, tested, or developed a compound having the following structure:

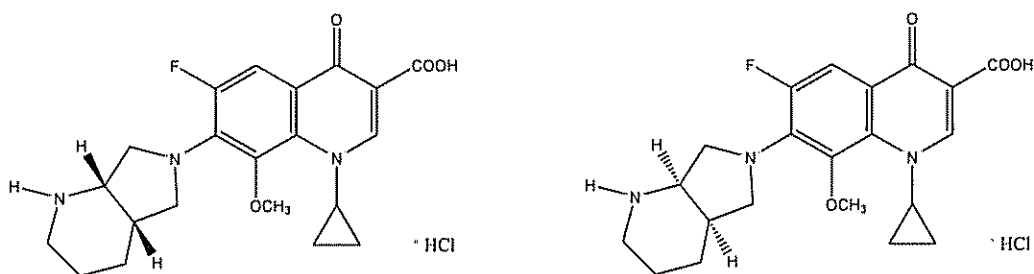


7. Whether the '830 patent does not list or reference any document which shows a different structure than that shown above in paragraph 6 for the term “Moxifloxacin.”

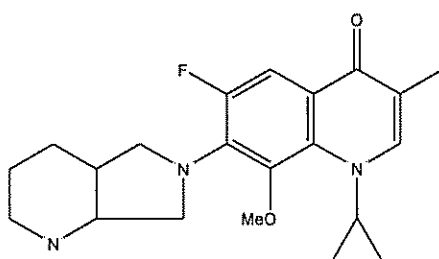
**B. Noninfringement**

1. Whether the active pharmaceutical ingredient in the product described in Teva's ANDA No. 78-073 contains compounds having both of the following structures, but not as a racemate:

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated



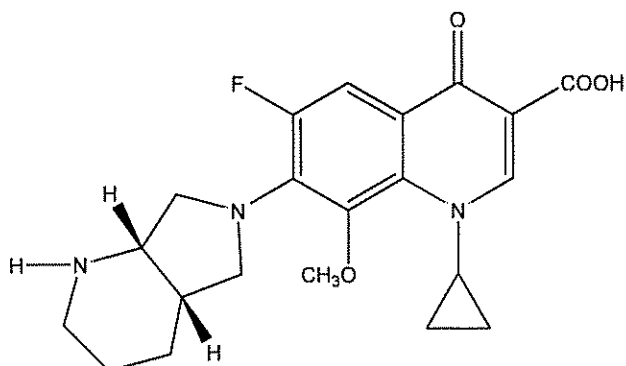
2. Whether the product described in Teva's ANDA No. 78-073 does not contain any ingredient having the following structure, or any pharmaceutically useful hydrate or salt thereof:



### C. Anticipation

If the Court adopts Alcon's proposed claim construction of claim 1 of the '830 patent, then the following facts remain to be litigated.

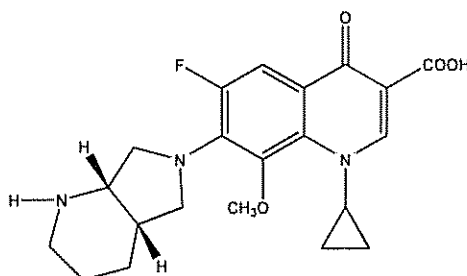
1. Whether U.S. Patent 5,607,942 discloses the following structure:



or a pharmaceutically utilizable hydrate or acid addition salt thereof.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

2. Whether claim 1 of the '942 patent is for a compound having the following structure:



and “acid addition salt[s] thereof.”

3. Whether the '942 patent discloses “ophthalmological” formulations of the compounds disclosed therein at column 56, line 27.

4. Whether the '942 patent states specifically that such formulations can be “eye ointments” at column 56, lines 28-29.

5. Whether the '942 patent states that such formulations “can be used for local therapy” at column 56, lines 29-30.

6. Whether “local therapy” includes topical delivery.

7. Whether, in the context of the present case, “ophthalmological” has the same meaning as “ophthalmic.”

8. Whether a person of ordinary skill in the art would understand that an “ophthalmological” formulation necessarily includes a pharmaceutically acceptable vehicle.

9. Whether the '942 patent discloses that the compounds disclosed therein can be present in “pharmaceutical formulations in a concentration of about 0.1 to 99.5, preferably about 0.5 to 95% by weight of the total mixture.”

10. Whether a composition having a concentration of 0.1 weight percent of the compounds disclosed in the '942 patent is disclosed by the '942 patent.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

11. Whether a composition having a concentration of 0.5 weight percent of the compounds disclosed in the '942 patent is disclosed by the '942 patent.

12. Whether a composition having a concentration of 1.0 weight percent of the compounds disclosed in the '942 patent is disclosed by the '942 patent.

13. Whether a person having ordinary skill in the art would understand from the '942 patent that compounds disclosed in the '942 patent could be used in an ophthalmic formulation in a concentration within the range of 0.1 to 1.0 weight percent.

14. Whether U.S. Patent 5,607,942 discloses formulations for the local administration of a compound or compounds disclosed in the '942 patent, including "ophthalmological" formulations, for example, "eye ointments," "solutions," and "drops," and whether such formulations are topical ophthalmic pharmaceutical compositions as specified in claim 1 of the '830 patent.

15. Whether U.S. Patent 5,607,942 discloses a variety of excipients, and references "the usual and customary excipients," for formulating pharmaceutically acceptable vehicles suitable for ophthalmic formulations such as solutions, suspensions, gels, and ointments, and whether the '942 patent thus discloses the "pharmaceutically acceptable vehicle" element of claim 1 of the '830 patent.

16. Whether U.S. Patent 5,607,942 discloses that the compounds disclosed therein "should preferably be present" "in a concentration of about 0.1[%]", "preferably about 0.5[%]" "by weight of the total mixture," and whether these concentrations are within the range recited in claim 1 of the '830 patent.

17. Whether one of ordinary skill in the art would understand that the '942 patent discloses a topical ophthalmic pharmaceutical composition comprising moxifloxacin or a

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

**D. Obviousness**

If the Court adopts Alcon's proposed claim construction of claim 1 of the '830 patent, then the following facts remain to be litigated.

**i. Person Having Ordinary Skill In The Art**

1. Whether the '830 patent pertains to the field of pharmaceuticals, particularly ophthalmic formulations.

2. Whether the person having ordinary skill in the art in the field to which the '830 patent is directed would have at least an entry-level (B.S. or PharmD.) in Pharmacy and also 5 to 10 years' experience formulating ophthalmic formulations.

3. Whether none of the inventors listed on the '830 patent have a Medical Doctorate degree.

**ii. The Scope And Content Of The Prior Art<sup>2</sup>**

1. Whether U.S. Patent No. 4,990,517 is prior art to the '830 patent.

2. Whether the certified file history of U.S. Patent No. 4,990,517, which includes the '517 patent, is prior art to the '830 patent.

3. Whether U.S. Patent No. 5,607,942 is prior art to the '830 patent.

4. Whether the '830 patent, at column 3, lines 49-51, refers to U.S. Patent No. 5,607,942 as providing "[f]urther details regarding the structure, preparation, and physical properties of Moxifloxacin and other compounds of formula (I)."

---

<sup>2</sup> Teva contends that the prior art shows at least 21 *prima facie* cases of the obviousness of claim 1 of the '830 patent. For completeness, these *prima facie* cases of obviousness are separately set forth in the following paragraphs



Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

5. Whether the file history of U.S. Patent No. 5,607,942 (U.S. Patent Application Serial No. 08/406,448), which includes the '942 patent, is prior art to the '830 patent.
6. Whether Remington: The Science and Practice of Pharmacy, 19<sup>th</sup> ed. (1995); Ch. 89: Ophthalmic Preparations (author: Gerald Hecht), pp. 1563-1579 (Mack Publishing Co., Easton, Pa.) is prior art to the '830 patent.
7. Whether Modern Pharmaceuticals, 2<sup>nd</sup> ed. (1990), Ch. 14: Design and Evaluation of Ophthalmic Pharmaceutical Products (Marcel Dekker, Inc., New York) is prior art to the '830 patent.
8. Whether *Snyder, et. al.*, "Ciprofloxacin-resistant Bacterial Keratitis," *Am. J. Ophthal.*, 114:336-338 is prior art to the '830 patent.
9. Whether *Forster*, "The Management of Infectious Keratitis As We Approach the 21<sup>st</sup> Century," *The CLAO Journal*, Vol. 24, No. 3, pp. 175-180 is prior art to the '830 patent.
10. Whether *Zurenko, et al.*, "Oxazolidinone antibacterial agents: development of the clinical candidates eperezolid and linezolid," *Ex. Opin. Invest. Drugs* (1997) 6(2): 151-158 is prior art to the '830 patent.
11. Whether *Borrmann et al.*, "Ofloxacin in Human Serum, Urine, and Tear Film After Topical Application," *Cornea* 11(3): 226-230 is prior art to the '830 patent.
12. Whether *Liu*, "Pharmacokinetics of Sparfloxacin in the Serum and Vitreous Humor of Rabbits: Physicochemical Properties That Regulate Penetration of Quinolone Antimicrobials," *Antimicrob. Agents Chemother.* 42: 1417-1423 is prior art to the '830 patent.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

13. Whether topical ophthalmic pharmaceutical compositions containing antibiotics, including fluoroquinolones, were known in the art prior to the invention of the subject matter claimed in claim 1 of the '830 patent.

14. Whether, before the priority date of the '830 patent, moxifloxacin was known to have antibiotic properties.

15. Whether, as of the priority date of the '830 patent, the use of topical ophthalmic quinolone formulations such as Ciloxan® and Ocuflox® was the standard of care in the treatment of conjunctivitis and keratitis and the prevention of post-operative keratitis and endophthalmitis.

16. Whether keratitis may be caused by *Pseudomonas aeruginosa* or *Staphylococcus aureus*.

17. Whether BAY 12-8039 is Bayer's name for the S,S enantiomer of moxifloxacin hydrochloride.

18. Whether the '942 patent discloses moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a topical ophthalmic pharmaceutical composition, in a pharmaceutically acceptable vehicle, and suggests to a person of ordinary skill in the art that the concentration of moxifloxacin in such a topical ophthalmic pharmaceutical composition could be within the range of 0.1 to 1.0 weight percent.

19. Whether the file history of the '942 patent would suggest to a person of ordinary skill in the art that, from Bayer's perspective, "of all the fluoroquinolones that we have investigated, the compound of claim 25 [i.e., moxifloxacin or a pharmaceutically useful hydrate or salt thereof] is the best tolerated that we have ever seen."

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

20. Whether the file history of the '942 patent, including the '942 patent itself, discloses or suggests to a person of ordinary skill in the art "moxifloxacin or a pharmaceutically useful hydrate or salt thereof" in a topical ophthalmic pharmaceutical composition, in a pharmaceutically acceptable vehicle, in a concentration within the range of 0.1 to 1.0 weight percent.

21. Whether Ciloxan® Ophthalmic Solution is prior art to the '830 patent.

22. Whether the entry for "Ciloxan Solution/Drops; Ophthalmic" in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutics Equivalence Evaluations (January 1, 1997 edition) is prior art to the '830 patent.

23. Whether the monograph for Ciloxan® from the 52<sup>nd</sup> edition of the Physicians' Desk Reference is prior art to the '830 patent.

24. Whether the monograph for Ciloxan® from the 50<sup>th</sup> edition of the Physicians' Desk Reference is prior art to the '830 patent.

25. Whether the active pharmaceutical ingredient in Ciloxan® Ophthalmic Solution is ciprofloxacin, which, like moxifloxacin, is a fluoroquinolone.

26. Whether, as of September 30, 1997, the concentration of ciprofloxacin in Ciloxan® Ophthalmic Solution was 0.3 weight percent.

27. Whether Ciloxan® Ophthalmic Solution discloses a topical ophthalmic pharmaceutical composition containing a fluoroquinolone (ciprofloxacin) in a concentration of 0.3 weight percent in a pharmaceutically acceptable vehicle.

28. Whether the '942 patent, in light of the formulation of Ciloxan® Ophthalmic Solution, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

29. Whether Ciloxan® Ophthalmic Ointment is prior art to the '830 patent.

30. Whether the entry for "Ciloxan Ointment; Ophthalmic" in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (1998 Cumulative Supplement 10 (Jan. '98-Oct. '98)) is prior art to the '830 patent.

31. Whether the active pharmaceutical ingredient in Ciloxan® Ophthalmic Ointment is ciprofloxacin, which, like moxifloxacin, is a fluoroquinolone.

32. Whether, as of September 30, 1998, the concentration of ciprofloxacin in Ciloxan® Ophthalmic Ointment was 0.3 weight percent.

33. Whether Ciloxan® Ophthalmic Ointment discloses a topical ophthalmic pharmaceutical composition containing a fluoroquinolone (ciprofloxacin) in a concentration of 0.3 weight percent in a pharmaceutically acceptable vehicle.

34. Whether the '942 patent, in light of the formulation of Ciloxan® Ophthalmic Ointment, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

35. Whether Ocuflox® Ophthalmic Solution is prior art to the '830 patent.

36. Whether the active pharmaceutical ingredient in Ocuflox® is ofloxacin, which, like ciprofloxacin and moxifloxacin, is a fluoroquinolone.

37. Whether, as of September 30, 1997, the concentration of ofloxacin in Ocuflox® was 0.3 weight percent.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

38. Whether Ocuflox® Ophthalmic Solution discloses a topical ophthalmic pharmaceutical composition containing a fluoroquinolone (ofloxacin) in a concentration of 0.3 weight percent in a pharmaceutically acceptable vehicle.

39. Whether the '942 patent, in light of the formulation of Ocuflox® Ophthalmic Solution, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

40. Whether Tobradex® Ophthalmic Suspension is prior art to the '830 patent.

41. Whether the active ingredient in Tobradex® Ophthalmic Suspension is tobramycin, an antibiotic.

42. Whether, as of September 30, 1997, the concentration of tobramycin in Tobradex Ophthalmic Suspension was 0.3 weight percent.

43. Whether Tobradex® Ophthalmic Suspension discloses a topical ophthalmic pharmaceutical composition containing an antibiotic in a concentration of 0.3 weight percent in a pharmaceutically acceptable vehicle.

44. Whether the '942 patent, in light of the formulation of Tobradex® Ophthalmic Suspension, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent.

45. Whether U.S. Patent No. 5,149,693 is prior art to the '830 patent.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

46. Whether U.S. Patent No. 5,149,693 discloses a topical ophthalmic pharmaceutical composition containing an antibiotic in a concentration in the range of 0.1 to 1.0 weight percent in a pharmaceutically acceptable vehicle.

47. Whether the '942 patent, in light of U.S. Patent No. 5,149,693, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent.

48. Whether *Firestone, B.A. et al.*, "Solubility characteristics of three fluoroquinolone ophthalmic solutions in an *in vitro* tear model," Int'l Journal of Pharmaceutics 164 (1998) 119-128 is prior art to the '830 patent.

49. Whether the formulations discussed in *Firestone* are prior art to the '830 patent.

50. Whether *Firestone, B.A. et al.*, "Solubility characteristics of three fluoroquinolone ophthalmic solutions in an *in vitro* tear model," Int'l Journal of Pharmaceutics 164 (1998) 119-128 discloses three separate topical ophthalmic pharmaceutical compositions, each containing either ciprofloxacin, norfloxacin, or ofloxacin (all three of which are fluoroquinolones) in a concentration of 0.3 weight percent, in a pharmaceutically acceptable vehicle.

51. Whether the '942 patent, in light of the *Firestone et al.* article, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

52. Whether *Schmitz et al.*, "Relationship between ciprofloxacin, ofloxacin, levofloxacin, sparfloxacin and moxifloxacin (BAY 12-8039) MICs and mutations in *grrA*, *grrB*, *gyrA*, and *gyrB* in 116 unrelated clinical isolates of *Staphylococcus aureus*," J. Antimicrob. Chemother., Vol. 41, pp. 481-484 is prior art to the '830 patent.

53. Whether the *Schmitz et al.*, article states, at page 481, that one of the proposed mechanisms of fluoroquinolone resistance is mutations in the *gyrA* and *gyrB* genes, which encode DNA gyrase.

54. Whether the *Schmitz et al.* article also states, at page 481, that another of the proposed mechanisms of fluoroquinolone resistance is mutations in the *grrA* and *grrB* genes, which encode DNA topoisomerase.

55. Whether the *Schmitz et al.* article also states, at page 484, that

In summary, ciprofloxacin was the least active compound, followed by ofloxacin, levofloxacin and sparfloxacin, and moxifloxacin was the most active, in response to all characterized mutations in *grrA*, *grrB*, *gyrA* and *gyrB*. Unlike the older fluoroquinolones, moxifloxacin was active against most *S. aureus* isolates tested and was less influenced by known mutations within the loci involved in fluoroquinolone resistance.

56. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have had no reason to doubt the information contained in the *Schmitz et al.* article.

57. Whether the '942 patent, in light of *Schmitz et al.*, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

58. Whether *Dalhoff et al.*, "In vitro activity of BAY 12-8039, a new 8-methoxyquinolone," *Chemotherapy*, Vol. 42, No. 6, pp. 410-425 (1996) is prior art to the '830 patent.

59. Whether the *Dalhoff et al.* article states at page 410, in reference to moxifloxacin, that "[a]s compared to ciprofloxacin, development of resistance was less pronounced."

60. Whether the *Dalhoff et al.* article discloses, at page 422, that "[e]ven ciprofloxacin-resistant, either methicillin-susceptible or methicillin-resistant *S. aureus* are inhibited by reasonable low concentrations of BAY 12-8039 ranging from 0.5 to 8 mg/l. This finding mirrors the highly improved intrinsic activity of BAY 12-8039 against staphylococci as compared to currently marketed quinolones."

61. Whether the *Dalhoff et al.* article discloses, at page 424, that "[t]he difference in kill kinetics-BAY 12-8039 exhibiting a concentration-dependent killing of *S. aureus* and *S. pneumonia* as opposed to the other quinolones tested-and in mutational frequencies of BAY 12-8039 and ciprofloxacin, respectively, suggest that these two quinolones might have different affinities to their target(s) and/or that BAY 12-8039 might interact with an additional target in gram-positive bacteria."

62. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have had no reason to doubt the information contained in the *Dalhoff et al.* article.

63. Whether the '942 patent, in light of *Dalhoff et al.*, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing



Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

64. Whether the poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" bearing Bates number BL005-019300 is prior art to the '830 patent.

65. Whether the poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" and referenced in the immediately preceding paragraph was presented at the 36<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, held on September 15-18 in New Orleans, Louisiana.

66. Whether the abstract entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" bearing Bates numbers BL014-011453 through BL014-011455 is prior art to the '830 patent.

67. Whether the poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" ("the Bayer poster") discloses that moxifloxacin hydrochloride had, at the time of the poster was presented, had been shown to be sufficiently safe such that it had entered Phase II of FDA clinical trials.

68. Whether the data in the Bayer poster show that moxifloxacin has better MIC activity against the ICB 25701, ATCC 29213, and 133 strains of *Staphylococcus aureus* than ofloxacin.

69. Whether the data in the Bayer poster show that moxifloxacin has better MIC activity against the Walter and ATCC 27853 strains of *Pseudomonas aeruginosa* than ofloxacin.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

70. Whether the data in the Bayer poster show that moxifloxacin has better MIC activity against the ICB 25701, ATCC 29213, and 133 strains of *Staphylococcus aureus* than ofloxacin.

71. Whether the Bayer poster discloses that moxifloxacin hydrochloride has a solubility in water of 24 mg/mL at 25°C.

72. Whether solubility of 24 milligrams per milliliter is sufficient for topical ophthalmic pharmaceutical compositions having concentrations from 0.1 to 1.0 weight percent.

73. Whether the Bayer poster, in light of the '942 patent, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

74. Whether the Bayer poster, in light of the formulation of Ciloxan® Ophthalmic Solution, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

75. Whether the Bayer poster, in light of the formulation of Ciloxan® Ophthalmic Ointment, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

76. Whether the Bayer poster, in light of the formulation of Ocuflox® Ophthalmic Solution, discloses or suggests to a person of ordinary skill in the art a topical

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

77. Whether the Bayer poster, in light of the formulation of Tobradex® Ophthalmic Suspension, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

78. Whether the Bayer poster, in light of U.S. Patent No. 5,149,693, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

79. Whether the Bayer poster, in light of the *Firestone et al.* article, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

80. Whether the Bayer poster, in light of *Schmitz et al.*, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

81. Whether the Bayer poster, in light of *Dalhoff et al.*, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

82. Whether the prior art taught a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing a fluoroquinolone antibiotic having a concentration within the range 0.1 to 1.0, in a pharmaceutically acceptable vehicle.

83. Whether the prior art provided the person of ordinary skill in the art with a reasonable expectation of success in making a topical ophthalmic pharmaceutical composition containing moxifloxacin, or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

84. Whether the Bayer poster, in light of Ciloxan®, Ocuflox®, and *Schmitz et al.*, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

85. Whether the Bayer poster, in light of Ciloxan®, Ocuflox®, and *Dalhoff et al.*, discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

86. Whether a combination of two or more of the following references:

- U.S. Patent 5,607,942

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

- The prosecution history of U.S. Patent 5,607,942
- Ciloxan® Ophthalmic Solution
- Ciloxan® Ophthalmic Ointment
- Tobradex® Ophthalmic Suspension
- U.S. Patent 5,149,693
- Ocuflox®
- *Firestone, B.A. et al.*, "Solubility characteristics of three fluoroquinolone ophthalmic solutions in an *in vitro* tear model," Int'l Journal of Pharmaceutics 164 (1998) 119-128
- *Schmitz et al.*, "Relationship between ciprofloxacin, ofloxacin, levofloxacin, sparfloxacin and moxifloxacin (BAY 12-8039) MICs and mutations in *grlA*, *grlB*, *gyrA*, and *gyrB* in 116 unrelated clinical isolates of *Staphylococcus aureus*," J. Antimicrob. Chemother., Vol. 41, pp. 481-484
- *Dalhoff et al.*, "In vitro activity of BAY 12-8039, a new 8-methoxyquinolone," Chemotherapy, Vol. 42, No. 6, pp. 410-425 (1996)
- The poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone"

discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

87. Whether the prior art as a whole discloses or suggests to a person of ordinary skill in the art a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

**iii. The Differences Between The Prior Art And Claim 1 Of The '830 Patent**

1. Whether the concentration of the active pharmaceutical ingredient in Vigamox® is 0.5 weight percent.
2. Whether the formulation described in Example 1 of the '830 patent is within the scope of claim 1 of the '830 patent.
3. Whether the only difference in ingredients between the formulation described in Example 1 of the '830 patent and the formulation of Ciloxan® Ophthalmic Solution is the substitution in Example 1 of moxifloxacin for the ciprofloxacin hydrochloride in Ciloxan® Ophthalmic Ointment.
4. Whether the concentration of ciprofloxacin hydrochloride in Ciloxan® Ophthalmic Solution is 0.35 weight percent.
5. The concentration of moxifloxacin in Example 1 of the '830 patent is 0.35 weight percent.
6. Whether the formulation described in Example 2 of the '830 patent is within the scope of claim 1 of the '830 patent.
7. Whether the only difference in ingredients between the formulation described in Example 2 of the '830 patent and the formulation of Tobradex® Ophthalmic Suspension is the substitution in Example 2 of moxifloxacin for tobramycin.
8. Whether the concentration of tobramycin in Tobradex® Ophthalmic Suspension is 0.3 weight percent.
9. Whether the concentration of moxifloxacin in Example 2 of the '830 patent is 0.3 weight percent.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

10. Whether the formulation described in Example 3 of the '830 patent is within the scope of claim 1 of the '830 patent.

11. Whether the only difference in ingredients between the formulation described in Example 3 of the '830 patent and the formulation of Ciloxan® Ophthalmic Ointment is the substitution in Example 3 of moxifloxacin for ciprofloxacin hydrochloride.

12. Whether the concentration of ciprofloxacin hydrochloride in Ciloxan® Ophthalmic Ointment is 0.35 weight percent.

13. Whether the concentration of moxifloxacin in Example 3 of the '830 patent is 0.35 weight percent.

14. Whether the formulation described in Example 4 of the '830 patent is within the scope of claim 1 of the '830 patent.

15. Whether the only difference in ingredients between the formulation described in Example 4 of the '830 patent and the formulation described in Example II of U.S. Patent No. 5,149,693 is the substitution in Example 4 of the '830 patent of moxifloxacin for "Tobramycin; Micronized, USP."

16. Whether the concentration of "Tobramycin; Micronized, USP" in Example II of U.S. Patent No. 5,149,693 is "3 mg + 7% excess" per gram of the composition.

17. Whether the concentration of moxifloxacin in Example 4 of the '830 patent is .3 weight percent.

18. Whether a concentration of .3 weight percent is equivalent to a concentration of 3 mg/mL.

19. Whether every element of claim 1 of the '830 patent is disclosed or suggested by the '942 patent

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

**iv. Motivation**

1. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have known, based on the disclosure in the Bayer poster that moxifloxacin hydrochloride was in Phase II clinical studies, that moxifloxacin hydrochloride had not exhibited unacceptable toxicity.

2. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have known, based on the Bremm declaration in the '942 patent's file history dated July 20, 1995, that Bayer considered moxifloxacin hydrochloride to have good tolerability.

3. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have known, based on the Bayer poster and the July 20, 1995 Bremm declaration, that moxifloxacin hydrochloride had not exhibited unacceptable toxicity.

4. Whether the safety information in the Bayer poster would have motivated a person of ordinary skill in the art to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

5. Whether the statements and data in the July 20, 1995 Bremm declaration would have motivated a person of ordinary skill in the art to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

6. Whether the safety information in the Bayer poster and the July 20, 1995 Bremm declaration would have motivated a person of ordinary skill in the art to make a topical



Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

7. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have known, based on the Bayer poster, that moxifloxacin hydrochloride was sufficiently soluble in water to be formulated in an ophthalmic pharmaceutical composition that would at least treat surface ophthalmic infections.

8. Whether the solubility information in the Bayer poster would have motivated a person of ordinary skill in the art to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle for the treatment of ophthalmic infections.

9. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have known, based on the data in the Bayer poster, that moxifloxacin hydrochloride exhibited better MIC against the ICB 25704, ATCC 29213, and 133 strains of *S. aureus* than either ciprofloxacin or ofloxacin.

10. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have known, based on the data in the Bayer poster, that moxifloxacin exhibited better MIC against the Walter and ATCC 27853 strains of *P. aeruginosa* than ofloxacin.

11. Whether the MIC data in the Bayer poster would have motivated a person of ordinary skill in the art to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle for the treatment of ophthalmic infections.

12. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have known, based on the *Schmitz et al.* article, that moxifloxacin hydrochloride was likely to be less prone to the development of bacterial resistance than other fluoroquinolones.

13. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art would have known, based on the *Dalhoff et al.* article, that moxifloxacin hydrochloride was less prone to the development of bacterial resistance than ciprofloxacin.

14. Whether the findings with respect to resistance in the *Schmitz et al.* article would have motivated a person of ordinary skill in the art to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle for the treatment of ophthalmic infections.

15. Whether the findings with respect to resistance in the *Dalhoff et al.* article would have motivated a person of ordinary skill in the art to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle for the treatment of ophthalmic infections.

16. Whether the findings with respect to resistance in the *Dalhoff et al.* and *Schmitz et al.* articles would have motivated a person of ordinary skill in the art to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle for the treatment of ophthalmic infections.

17. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art, based on the marketing of Ciloxan® Ophthalmic Solution, would have been motivated to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle for the treatment of ophthalmic infections.

18. Whether, as of the priority date of the '830 patent, a person of ordinary skill in the art, based on the marketing of Ocuflox® Ophthalmic Solution, would have been motivated to make a topical ophthalmic pharmaceutical composition containing moxifloxacin or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle for the treatment of ophthalmic infections.

19. Whether the prior art provided the person of ordinary skill in the art with a reasonable expectation of success in making a topical ophthalmic pharmaceutical composition containing moxifloxacin, or a pharmaceutically useful hydrate or salt thereof, in a concentration within the range of 0.1 to 1.0 weight percent, in a pharmaceutically acceptable vehicle.

20. Whether the invention claimed in claim 1 of the '830 patent was the product of common sense and ordinary skill.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

**v. Secondary Considerations**

1. Whether evidence of secondary considerations of nonobviousness is inadequate to overcome the overwhelming *prima facie* case of obviousness of claim 1 of the '830 patent.
2. Whether commercial sales data for Avelox® is not relevant to the obviousness of claim 1 of the '830 patent.
3. Whether evidence of any unexpected desirable properties of any composition within the scope of claim 1 is not commensurate with the scope of claim 1 of the '830 patent.
4. Whether Alcon has shown evidence of any unexpected desirable properties of any composition within the scope of claim 1 of the '830 patent.
5. Whether evidence of satisfaction of a long-felt but unmet need satisfied by any composition within the scope of claim 1 is not commensurate with the scope of claim 1 of the '830 patent.
6. Whether Alcon has shown evidence that any composition within the scope of claim 1 satisfies any long-felt but unmet need.
7. Whether evidence of commercial success of any composition within the scope of claim 1 is not commensurate with the scope of claim 1 of the '830 patent.
8. Whether Alcon has shown commercial success of any composition within the scope of claim 1 of the '830 patent.
9. Whether evidence of praise for any composition within the scope of claim 1 of the '830 patent from practitioners in the field is not commensurate with the scope of claim 1 of the '830 patent.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

10. Whether Alcon has shown evidence of praise from practitioners in the field of any composition within the scope of claim 1 of the '830 patent.

11. Whether skepticism of any composition within the scope of claim 1 of the '830 patent in the field is not commensurate with the scope of claim 1 of the '830 patent.

12. Whether Alcon has shown evidence of skepticism in the field of any composition within the scope of claim 1 of the '830 patent.

13. Whether evidence of objective indicia of nonobviousness of any composition within the scope of claim 1 of the '830 patent is commensurate with the scope of claim 1 of the '830 patent.

14. Whether Alcon has shown evidence of any objective indicia of nonobviousness of any composition within the scope of claim 1 of the '830 patent.

15. Whether the Bayer poster provides a person of ordinary skill in the art with a reasonable expectation that moxifloxacin hydrochloride would be effective in treating ophthalmic infections caused by *S. aureus* and *P. aeruginosa*, in addition to other ocular pathogens.

16. Whether the Bayer poster provides a person of ordinary skill in the art with a reasonable expectation that moxifloxacin hydrochloride would be effective in treating ophthalmic infections caused by *S. aureus* and *P. aeruginosa*, in addition to other ocular pathogens.

17. Whether the Bayer poster provides a person of ordinary skill in the art with a reasonable expectation that moxifloxacin hydrochloride is sufficiently soluble in water such that it could be formulated into an ophthalmic solution having sufficient pharmacokinetics to effectively treat at least surface ocular infections.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

18. Whether the Bayer poster provides a person of ordinary skill in the art with a reasonable expectation that moxifloxacin hydrochloride had demonstrated sufficient safety to move to Phase II FDA clinical trials.

19. Whether the *Dalhoff et al.* article provides a person of ordinary skill in the art with a reasonable expectation that moxifloxacin would be sufficiently resistant to the development of bacterial resistance.

20. Whether the *Schmitz et al.* article provides a person of ordinary skill in the art with a reasonable expectation that moxifloxacin would be sufficiently resistant to the development of bacterial resistance.

**E. Best Mode**

1. Whether Dr. Stroman concealed from the public his best mode of carrying out the invention, which used Bay 12-8039.

2. Whether the '830 patent claims priority to September 30, 1998.

3. Whether there was no reduction to practice of the invention claimed in the '830 patent before September 30, 1998.

4. Whether Dr. David Stroman is an inventor of the subject matter claimed in the '830 patent.

5. Whether Dr. Stroman testified on behalf of Alcon under Fed. R. Civ. P. 30(b)(6).

6. Whether Dr. Stroman attended a conference before 1998 at which he observed a poster presentation related to BAY 12-8039.

7. Whether Dr. Stroman requested a sample of BAY 12-8039 from Bayer on February 10, 1998.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

8. Whether, as reflected in Dr. Stroman's Compound Request dated February 10, 1998, Dr. Stroman knew as of that date that BAY 12-8039 referred to the hydrochloride salt of moxifloxacin.

9. Whether the only form of moxifloxacin known to Dr. Stroman before September 30, 1998 was BAY 12-8039.

10. Whether the hydrochloride salt of moxifloxacin, therefore, was Dr. Stroman's best mode of practicing the invention claimed in claim 1 of the '830 patent.

11. Whether the hydrochloride salt of moxifloxacin is not disclosed in the '830 patent.

**F. Enablement**

1. Whether the '830 patent does not describe how to make a topical ophthalmic pharmaceutical composition.

2. Whether the ability to make a topical ophthalmic pharmaceutical composition from a list of ingredients is not a skill possessed by each and every person of ordinary skill in the art as the person of ordinary skill in the art has been defined by Alcon's experts.

3. Whether the person of ordinary skill in the art, as defined by Alcon, would necessarily be able to make a composition within the scope of claim 1 of the '830 patent without undue experimentation.

**G. Written Description**

1. Whether the specification of the '830 patent would be understood by one of ordinary skill in the art to require the use of a preservative, separate from the active moxifloxacin ingredient, in the compositions of claim 1.

Exhibit 3: Teva's Statement Of Issues Of Fact That Remain To Be Litigated

2. Whether claim 1 is broader than the supporting disclosure because it does not require the inclusion in the covered compositions of a preservative separate from the active moxifloxacin ingredient.

3. Whether a person of ordinary skill would understand from the '830 patent's written description that the inventors had in their possession only moxifloxacin compositions which contain a separate preservative in addition to the active moxifloxacin ingredient.

4. Whether a person of ordinary skill reading the '830 patent's written description would understand that compositions not containing a preservative separate from moxifloxacin were ready for patenting.

**V. EXCEPTIONAL CASE**

1. Whether Bayer's assertion of the unenforceable '942 patent against Teva renders this an "exceptional case" in accordance with 35 U.S.C. § 285.

2. Whether Teva should accordingly be awarded costs and attorneys' fees.

3. Whether Alcon's assertion of claim 1 of the '830 patent in this action is unjustified, such that this is an "exceptional case."

4. Whether Teva should accordingly be awarded costs and attorneys' fees.



# EXHIBIT 4

**EXHIBIT 4**

**PLAINTIFFS' STATEMENT OF ISSUES OF LAW  
THAT REMAIN TO BE LITIGATED**

To the extent that Bayer and Alcon's statement of issues of fact contain issues of law, those issues are incorporated herein by reference. Should the Court determine that any issue identified in this list as an issue of law is more properly considered an issue of fact, Bayer and Alcon incorporate such issues by reference into its statement of issues of fact.

During the course of the litigation, Teva asserted numerous defenses in response to Bayer and Alcon's assertions of infringement that Teva has indicated it no longer intends to assert at trial. In particular, Teva asserted that the '517 and '942 patents were invalid for obviousness, lack of enablement and lack of written description. During expert discovery, however, Teva's counsel indicated that Teva no longer intends to pursue these defenses. Teva additionally has clarified that its only basis for asserting that the claims of the '942 patent are invalid for double patenting over the '517 patent is that "(a) the Asserted claims of the '942 patent are from Group IV, the same Group as claims of the '517 patent, and (b) the third sentence of 35 U.S.C. § 121 does not apply." Further, at the close of expert discovery, Teva added three new invalidity defenses for the '830 patent—failure to satisfy the best mode requirement, lack of written description, and non-enablement.

Bayer and Alcon's identification of the issues of fact that remain to be litigated is based in part on their current understanding of the arguments Teva is likely to make in attempting to support its non-infringement, invalidity, and unenforceability defenses, based upon the pleadings and discovery in the action to date. To the extent Teva attempts to introduce different or additional facts to meet its burden of proof, Plaintiffs reserve the right to object to and/or contest those facts, and to present any and all rebuttal evidence in response to those facts.

## I. CLAIM CONSTRUCTION

“[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The Court should construe a claim term according to “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention,” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*), unless a person of ordinary skill in the art would understand the patentee to have re-defined the term in a manner that deviates from the ordinary meaning, *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005) (“We have repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term.”). With these legal principles in mind, the claim construction issues to be litigated are as follows:

1. Whether claims 1 and 2 of the '517 patent encompass any compound defined by the structural formulas presented in the claims—*i.e.*, any compound possessing the connectivity of atoms set forth in the claims, without limitation to a particular stereochemistry, including all stereoisomers, individually or any combination thereof.

2. Whether the phrase “substantially free” as used in claims 1, 3, and 5 of the '942 patent means “largely, but not necessarily, free.” *See, e.g., Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, No. 2:05cv421, slip op. at 10-24 (E.D. Va. May 11, 2006) (Markman Order); *UCB Societe Anonyme v. Mylan Labs., Inc.*, No. 1:04-cv-683-WSD, 2006 U.S. Dist. LEXIS 39393, at \*21-25 (N.D. Ga. June 14, 2006); *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1365-69 (Fed. Cir. 2001); *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1360-61 (Fed. Cir. 2003); *Tenneco Auto. Operating Co. v. Visteon Corp.*, No. 03-1030 (SLR), 2005 U.S. Dist. LEXIS

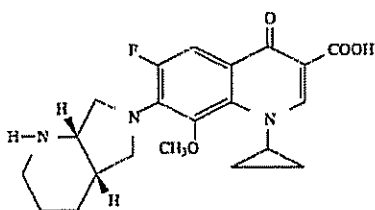
12738, at \*19 (D. Del. June 28, 2005); *Safas Corp. v. Etura Premier, LLC*, 293 F. Supp. 2d 436, 440 (D. Del. 2003).

3. Whether claim 2 of the '942 patent encompasses any compound defined by the structural formula depicted in the claim—i.e., any compound possessing the connectivity of atoms set forth in the claim, without limitation to a particular stereochemistry, including all stereoisomers, individually or any combination thereof.

4. Whether the prosecution histories at issue support Bayer's construction of the '517 and '942 patent claims.

5. Whether the prosecution histories at issue evidence that Bayer did not clearly and unmistakably modify the generally accepted understanding of (a) the structures recited in claims 1 and 2 of the '517 and claim 2 of the '942 patent, and (b) the phrase "substantially free" in claim 1 of the '942 patent. *See, e.g., Omega Eng'g Corp. v. Raytek, Inc.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003).

6. Whether the term "moxifloxacin" as used in claim 1 of the '830 patent has the ordinary, accepted meaning for that word, the compound:



## II. INFRINGEMENT

The infringement inquiry is a two-step process: the first step is to construe the claims, and the second step is to compare the accused product to the construed claims and determine whether each element recited by the claim is present in the accused product either literally or by equivalents. *See Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335,

1341 (Fed. Cir. 2003). Where all of the limitations of the claim are met, additional features do not avoid infringement. *See, e.g., N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 945 (Fed. Cir. 1990) (per curiam); *Radio Steel & Mfg. Co. v. MTD Prods., Inc.*, 731 F.2d 840, 848 (Fed. Cir. 1984); *cf. Vulcan Eng'g Co. v. FATA Aluminium, Inc.*, 278 F.3d 1366, 1375-76 (Fed. Cir. 2002).

The doctrine of equivalents applies when the equivalent represents an “insubstantial” change from the claim language. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 610 (1950). “[A] patentee may invoke [the] doctrine [of equivalents] to proceed against the producer of a device ‘if it performs substantially the same function in substantially the same way to obtain the same result.’” *Id.* at 608 (quoting *Sanitary Refrigeration Co. v. Winters*, 280 U.S. 30, 42 (1929)); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997).

A requirement for receiving a patent term extension is that the patent “claims a product, a method of using a product, or a method of manufacturing a product.” 35 U.S.C. § 156. Issuance of a patent term extension constitutes a determination by the Patent Office that the patent “does claim the active ingredient” of the product, and that determination is entitled to deference.

*Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1373 (Fed. Cir. 2003).

### **III. PRESUMPTION OF VALIDITY/CLEAR AND CONVINCING EVIDENCE**

Every issued patent claim is presumed valid. 35 U.S.C. § 282. A challenger bears the burden of establishing the invalidity of each asserted claim. *Id.*; *see also Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1358 (Fed. Cir. 1984). Invalidity and unenforceability must be proven by clear and convincing evidence. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376 (Fed. Cir. 2001); *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 744 (Fed. Cir. 2002); *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991). Where

invalidity is asserted on the basis of a reference considered by the Patent Office during prosecution of the patent, a challenger “bears an even heavier burden to prove invalidity.” *Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1368 (Fed. Cir. 2004).

#### IV. DOUBLE PATENTING

##### A. **Types of Double Patenting Recognized by Law.**

The law recognizes two bases for invalidation of a claim for double patenting. *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278 (Fed. Cir. 1992); *Bayer AG v. Dr. Reddy's Labs., Ltd.*, 518 F. Supp. 2d 617, available at 2007 U.S. Dist. LEXIS 79108, at \*54 (D. Del. 2007) (“There are two forms of the proscription against double patenting.”). The first, “[statutory] double patenting” (often called “same invention double patenting”) provides that a later-issued patent cannot claim the identical subject matter claimed in an earlier-issued patent with the same assignee. *In re Longi*, 759 F.2d 887, 892-93 (Fed. Cir. 1985) (“Whoever invents or discovers any new and useful process . . . may obtain a patent therefor” (emphasis in original) (quoting 35 U.S.C. § 101)); *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970).

The second basis for double patenting, often referred to generically as “non-statutory” double patenting, applies when “claims in a later patent . . . are not patentably distinct from claims in a commonly owned earlier patent.” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001); *In re Longi*, 759 F.2d at 892. In the double-patenting context, a “later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.” *Eli Lilly*, 251 F.3d at 968; *see also Gen. Foods Corp.*, 972 F.2d at 1279 (the phrases “‘patentably distinguishable,’ ‘patentable distinctions,’ and ‘whether such differences would have been obvious to one of ordinary skill in the art’” are “all equivalent”).

## **B. Non-Statutory Obviousness-Type Double Patenting.**

Obviousness-type double patenting (as opposed to non-statutory double patenting based on anticipation by an earlier claim) is concerned with whether later-issued claims are rendered obvious by earlier-issued claims, which “is analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. § 103, except that the patent principally underlying the double patenting rejection is not considered prior art.” *Longi*, 759 F.2d at 892 n.4 (alteration in original & internal quotation marks omitted). Unlike an obviousness inquiry under § 103, obviousness-type double patenting “depends entirely on what is *claimed* in an [earlier-]issued patent.” *In re Bartfeld*, 925 F.2d 1450, 1453 (Fed. Cir. 1991). The disclosure in the earlier specification is irrelevant to the inquiry. *Vogel*, 422 F.2d at 442.

The same underlying factual inquiries which are relevant to an obviousness determination under § 103 are relevant to the consideration of obviousness-type double patenting. *See, e.g., Studiengesellschaft Kohle mbH v. N. Petrochem. Co.*, 784 F.2d 351, 355 (Fed. Cir. 1986) (per curiam) (party asserting double patenting “offered no evidence of the scope and content of the [prior] art . . . the level of skill in the art, or what would have been obvious to a person skilled in the art”); *In re Zickendraht*, 319 F.2d 225, 232-33 (C.C.P.A. 1963) (Rich, J., concurring).

### **1. Consideration of the Properties of a Claimed Compound.**

The properties of a claimed compound must be considered in determining whether it is an obvious variant of an earlier-claimed compound. “From the standpoint of patent law, a compound and all of its properties are inseparable[.]” *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963). “[T]he patentability of [a compound] does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. There is no basis in law for ignoring any property in making such a comparison.” *Id.*; *see also, e.g., In re Lalu*, 747 F.2d 703, 707 (Fed. Cir. 1984) (“[A] relevant property of a compound

cannot be ignored in the determination of non-obviousness.”); *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987).

## 2. Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC.

*Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003) was “a case involving nonstatutory double patenting based upon anticipation under § 102 rather than obviousness under § 103.” *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 364 F. Supp. 2d 820, 911 (S.D. Ind. 2005) (citing *Geneva*, 349 F.3d at 1384). Footnote 1 of *Geneva* stated:

The distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting include:

1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;
2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;
3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.

“This interpretation makes sense in view of the law of anticipation, which does not require evidence of motivation to modify and objective evidence of nonobviousness.” *Zenith Goldline*, 364 F. Supp. 2d at 911; *see also In re Paulsen*, 30 F.3d 1475, 1482 n.11 (Fed. Cir. 1994) (“[E]vidence of nonobviousness is irrelevant for patentability purposes when an invention is anticipated under [35 U.S.C.] section 102.”). No argument of anticipation-based double patenting is presented here.

Decisions of the Federal Circuit and its predecessor have considered issues of *prima facie* obviousness (including motivation) and unexpected properties in the context of non-statutory double patenting contentions based on obviousness. *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 943 (Fed. Cir. 1992) (“Given the structure and properties of the components claimed in [the two



earlier-issued patents], there would have been no suggestion in the art (and, hence, it would not have been obvious) to modify those structures in order to achieve the compounds of [the patents-in-suit].”); *In re Baird*, 348 F.2d 974, 979 (C.C.P.A. 1965) (“This [double-patenting] problem may also be stated to be whether it would have been obvious to one of ordinary skill to modify the process of the patent claims by eliminating the irradiation step.”); *In re Emert*, 124 F.3d 1458, 1462 (Fed. Cir. 1997) (looking for “some indication of unexpected properties” in assessing whether the claimed invention was invalid for non-statutory double patenting); *Longi*, 759 F.2d at 896 (looking to a declaration concerning unexpected results to assess non-statutory double patenting); *Papesch*, 315 F.2d at 391; *Lalu*, 747 F.2d at 707.

### C. Section 121.

The third sentence of Title 35, Section 121 provides:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121. This provision provides an exception to the usual double patenting analysis set forth above, and necessarily precludes a finding of double patenting, where the later-filed application “was filed as a result of a restriction requirement and is consonant with that restriction requirement.” *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1347-48 (Fed. Cir. 2004). Consonance requires that the line of demarcation between the different restriction groups be respected, *i.e.*, the later patent claims must not include subject matter from the restriction group claimed in the earlier patent. *See Symbol Techs.*, 935 F.2d at 1579. Where the exception of Section 121 does not apply, the court conducts the usual double

patenting inquiry—whether the invention claimed in the later patent is patentably distinct from the earlier patent. *See, e.g., Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996) (“However, even if such consonance is lost, double patenting does not follow if the requirements of § 121 are met *or if the claims are in fact patentably distinct.*” (emphasis added)); *Tex. Instruments Inc. v. U.S. Int’l Trade Comm’n*, 988 F.2d 1165, 1179 (Fed. Cir. 1993) (“Moreover, even if there were no consonance due to a breach of the restriction requirement, respondents’ contentions on the ultimate obviousness-type double patenting inquiry would fail. Claims [of the later] patent are patentably distinct from claim[s] of the [earlier] patent.”); *Symbol Techs.*, 935 F.2d at 1580-81 (“Furthermore, even if there had been a breach of the restriction requirement, we would reject Opticon’s argument on the ultimate obviousness-type double patenting inquiry: whether the claims of the [later] patent are patentably distinct from the claims of the [earlier] patent.”); *see also Emert*, 124 F.3d at 1462 (“In spite of the parties’ eagerness to conform the round-peg facts of the case into semantic, square holes, the critical inquiry remains whether the claims in the [later] application define an obvious variation of the invention claimed in the [earlier] patent.”).

The inclusion of various compounds in a Markush group indicates that the compounds possess a common utility and therefore may be claimed together, not that they are patentably indistinct from one another. *See, e.g., Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003); *In re Harnisch*, 631 F.2d 716, 720-24 (C.C.P.A. 1980); *In re Driscoll*, 562 F.2d 1245, 1249 (C.C.P.A. 1977).

## V. INDEFINITENESS

A patent specification must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, ¶ 2. “Indefiniteness requires a determination whether those skilled in the art

would understand what is claimed.” *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007). If a claim is amenable to construction and is not insolubly ambiguous, it is not indefinite. *See id.*; *see also Aero Prods. Int’l, Inc. v. Intex Rec. Corp.*, 466 F.3d 1000, 1016 (Fed. Cir. 2006). As such, “the definiteness of claim terms depends on whether those terms can be given any reasonable meaning.” *Young*, 492 F.3d at 1346 (quotation marks omitted).

When a claim term is expressed in general descriptive words, it is generally improper to limit the term to a numerical range. *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). Courts repeatedly have found the term “substantial” to be a “meaningful modifier” that is capable of construction and hence not insolubly ambiguous. *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 907 (Fed. Cir. 2005); *Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

## VI. ENFORCEABILITY

“A party seeking to have a patent declared unenforceable has a heavy burden to meet.” *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003). To establish inequitable conduct, the challenger must establish by clear and convincing evidence that an individual with a duty of disclosure withheld material information or misrepresented material facts with the intention of misleading the patent examiner. *See Monsanto Co. v. Bayer Bioscience N.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004); *Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000); *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d at 744. Once materiality and intent have been established, the court must weigh those factors “in light of all of the circumstances to determine whether the applicant’s conduct is so culpable that the patent should be unenforceable.” *Juicy Whip*, 292 F.3d at 744; *see also Monsanto*, 363 F.3d at 1239. A low level of materiality requires a higher finding of intent, and vice-versa. *Purdue Pharma L.P.*

*v. Endo Pharms. Inc.*, 438 F.3d 1123, 1128-29, 1134-35 (Fed. Cir. 2006); *see also Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006).

#### **A. Materiality.**

The Federal Circuit has held that there are as many as five potential standards for materiality which may be applicable:

- the standard set forth in the current version of 37 C.F.R. § 1.56(b), which states that information is material if it (a) establishes, by itself or in combination with other information, a *prima facie* case of unpatentability, or (b) refutes, or is inconsistent with, a position the applicant takes in asserting an argument of patentability or opposing an argument of unpatentability;
- the objective “but for” standard, where the misrepresentation or omission was so material that the patent should not have issued;
- the subjective “but for” test, where the misrepresentation or omission actually caused the examiner to approve the patent application when he would not otherwise have done so;
- the “but it may have” standard, where the misrepresentation or omission may have influenced the patent examiner in the course of prosecution; and
- the “reasonable examiner” standard of the pre-1992 version of 37 C.F.R. § 1.56(b), where information is considered material if “there is a substantial likelihood that a reasonable examiner would consider [the information] important in deciding whether to allow the application to issue as a patent.” *Digital Control*, 437 F.3d at 1314-16 (quotation marks omitted).

Where test data is not inconsistent with a position taken during prosecution, it is not material. *See Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1377-78 (Fed. Cir. 2006). Courts should examine the allegedly withheld test data in the context of all data available to the applicant when making such a determination. *See id.*

#### **B. Intent.**

A party alleging inequitable conduct must demonstrate that a person with a duty of disclosure acted “with the specific intent to mislead” the PTO. *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1259 (Fed. Cir. 2000). There must be clear and convincing evidence that the applicant made a deliberate decision to withhold known material information. *See Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1329 (Fed. Cir. 1998). “Intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.” *Upjohn*, 225 F.3d at 1312 (quotation marks omitted); *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996).

### **VII. ANTICIPATION**

Anticipation under section 102 “requires that there be an identity of invention, which presents a question of fact . . . .” *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619 (Fed. Cir. 1985). A claim to a product is anticipated if all of the elements recited in the claim are present within the four corners of a single prior art reference. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1335 (Fed. Cir. 2002); *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

The elements of the invention taught by a single prior art reference must be “arranged as in the claim.” *Structural Rubber*, 749 F.2d at 716 (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). “The statutory language mandates such an approach. Section 102 speaks in terms of *the invention* having been known or used by others, or patented or

described in a printed publication [and] Section 103 provides that a patent may not be obtained “though *the invention* is not *identically* disclosed or described *as set forth in Section 102*.” *Id.* (footnote omitted); *accord In re Meyer*, 599 F.2d 1026, 1031-32 (C.C.P.A. 1979) (requiring “identical[]” disclosure for anticipation). The court cannot randomly pick and choose elements from different parts of a prior art reference and string together the claimed invention. *Alkzo N.V. v. U.S. Int’l Trade Comm’n*, 808 F.2d 1471, 1480 (Fed. Cir. 1986); *In re Arkley*, 455 F.2d 586, 587-89 (C.C.P.A. 1972) (same); *In re Ruschig*, 343 F.2d 965, 974 (C.C.P.A. 1965) (rejecting “highlight anticipations with the guidance of an applicant’s disclosures”).

The prior art reference also must contain enough information to put a person of ordinary skill in the art in possession of the claimed invention without undue experimentation. *Impax Labs.*, 468 F.3d at 1384 (Rader, J., concurring); *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 496 F. Supp.2d 428, 431-33 (D. Del. 2007); *see also Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1055 (Fed. Cir. 2003). In a reference that discloses millions of possible compositions, for a person of skill in the art to be in possession of any one composition, there must be some suggestion or “blaze mark[]” leading that person to the composition. *In re Ruschig*, 379 F.2d 990, 993-96 (C.C.P.A. 1967); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996).

“Selection inventions are ubiquitous in patent law.” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1340 (Fed. Cir. 2003). As such, the disclosure of a broad range does not anticipate a specific range contained within that range, as “[t]here may be many species encompassed within a genus that are not disclosed by a mere disclosure of the genus.” *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 998-1000 (Fed. Cir. 2006); *accord In re Meyer*, 599 F.2d at 1031-32 (reversing finding of anticipation because genus did not identically disclose species); *Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1270 (disclosure

of a genus does not prevent patenting a species member of the genus); *Metabolite*, 370 F.3d at 1368. Where the disclosed range is broader than and fully encompasses the specific range claimed in the patent at issue, “no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim.” *Atofina*, 441 F.3d at 999. In addition, disclosure of one range does not disclose an overlapping range. *Id.* at 1000. Finally, the disclosure of a range does not constitute a specific disclosure of any particular number in the range, including the endpoints of the range. *Id.*

### VIII. OBVIOUSNESS

Section 103 forbids issuance of a patent when “ the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103; *accord KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007); *United States v. Adams*, 383 U.S. 39, 51-52 (1966). Obviousness is a legal determination based on several underlying issues of fact: (1) the scope and content of the prior art; (2) the level of skill of a person of ordinary skill in the art; (3) the differences between the claimed invention and the teachings of the prior art; and (4) any objective indicia of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 14, 17-18 (1966). In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety. *See Schenck, A.G. v. Nortron Corp.*, 713 F.2d 782, 785 (Fed. Cir. 1983). Obviousness is determined as of the time of the invention, from the viewpoint of a hypothetical person of ordinary skill in the art. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is



likely the product not of innovation but of ordinary skill and common sense.” *KSR*, 127 S.Ct. at 1742. However, when there is a broad selection of possible options and the one chosen was no more likely than any other to be successful, the opposite is true. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1359, 1360, 1362 (Fed. Cir. 2007). And, in that situation, the fact that the selection made works “in an unexpected and fruitful manner” supports a conclusion that it was non-obviousness. *KSR*, 127 S.Ct. at 1740; *accord Adams*, 383 U.S. at 51-52; *Takeda Chem. Indus., Ltd.*, 492 F.3d at 1360. This is particularly so when there is no reasonable expectation that the selection would solve the problems addressed by the invention. *See Takeda Chem. Indus., Ltd.*, 492 F.3d at 1362 (upholding non-obviousness determination, in part, because “no reasonable expectation” that subject matter would overcome toxicity problem). A disclosure of a genus does not render a claim to a particular species obvious. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 869 (Fed. Cir. 2003); *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995); *In re Baird*, 16 F.3d 380, 382-83 (Fed. Cir. 1994).

“Section 103 requires a fact-intensive comparison of the claimed [subject matter] with the prior art rather than the mechanical application of one or another *per se* rule.” *In re Ochiai*, 71 F.3d 1565, 1571 (Fed. Cir. 1995).

#### **A. Determining the Person of Ordinary Skill in the Art.**

The issue of obviousness is determined entirely with reference to a hypothetical “person having ordinary skill in the art.” *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454-55 (Fed. Cir. 1985) (quotation marks omitted). “Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983)



(citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381-82 (Fed. Cir. 1983)). “Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case.” *Id.* at 696-97.

**B. Invalidity Allegations Based on Art that Was Considered by the Patent Office.**

Proving invalidity “is especially difficult when the prior art was before the PTO examiner during prosecution of the application.” *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990). Parties asserting invalidity have “the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.” *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

**C. Reason To Select the Prior Art References**

One cannot use “the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight.” *Ecolchem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1371-72 (Fed. Cir. 2000) (quotation marks omitted); *see also Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988). There must be some other reason to select the various prior art references relied upon in the obviousness analysis. *KSR*, 127 S. Ct at 1740-41. “Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.” *Id.*

(citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (alteration in original))).

#### **D. References that Teach Away.**

All of the prior art, including that which “teaches away” from the claimed invention, must be considered in assessing the alleged obviousness of a claimed invention. *United States v. Adams*, 383 U.S. 39, 51-52 (1966); *In re Sullivan*, 498 F.3d 1345, 1351-53 (Fed. Cir. 2007); *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1552-53 (Fed. Cir. 1983); *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1359-60 (Fed. Cir. 1999). “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

#### **E. Unexpected Properties.**

“[U]nexpected results,” *i.e.*, a showing that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected, can rebut a prima facie case of obviousness. *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (quotation marks omitted). “The basic principle behind this rule is straightforward—that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.” *Id.* When unexpected results are used as evidence

of nonobviousness, the results must be shown to be unexpected compared with the closest prior art. *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

Unexpected properties of “a broader claimed range can, in certain instances, be proven by a narrower range of data.” *In re Kollman*, 595 F.2d 48, 56 (C.C.P.A. 1979). “Often, one having ordinary skill in the art may be able to ascertain a trend in the exemplified data which would allow him to reasonably extend the probative value thereof. The proof, thus considered, might then be sufficient to rebut a PTO holding of prima facie obviousness.” *Id.*; see also *E.I. Du Pont de Nemours & Co. v. Phillips Petrol. Co.*, 656 F. Supp. 1343, 1368 (D. Del. 1987) (in assessing unexpected properties, “any gap may be effectively covered by *trends* discernible by a worker skilled in the art from a large quantity of existing data”), *vacated on other grounds*, 849 F.2d 1430 (Fed. Cir. 1988).

When considering the unexpected use of a novel composition, an important focus includes “unexpected result[s] from use of the claimed composition, how the prior art taught away from the composition, and how a long-felt need existed for a new . . . composition.” *Sullivan*, 498 F.3d at 1352-53. The issue “is not whether a claim recites a new use, but whether the subject matter of the claim possesses an unexpected use. That unexpected property is relevant[.]” *Id.* at 1353.

#### **F. Objective Indicia of Non-Obviousness.**

Objective indicia of non-obviousness must be considered in an obviousness determination. *WMS Gaming Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999); *In re Johnston*, 435 F.3d 1381, 1385 (Fed. Cir. 2006); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985). Objective evidence of non-obviousness includes commercial success, long-felt but unmet need, failure of others, and licenses of the patented invention to third parties. See *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). A

patentee can rely on unexpected properties not known or disclosed at the time of the invention to rebut a prima facie case of obviousness. *Knoll Pharm. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2005) (“There is no requirement that an invention's properties and advantages were fully known before the patent application was filed, or that the patent application contains all of the work done in studying the invention, in order for that work to be introduced into evidence in response to litigation attack. Nor is it improper to conduct additional experiments and provide later-obtained data in support of patent validity.”).

#### **IX. NON-ENABLEMENT**

An enabling specification requires the patent to “teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.” *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1185 (Fed. Cir. 2002) (internal quotation marks omitted). To be enabled, the specification need not “explain every detail” since the patent “is speaking to those skilled in the art.” *DeGeorge v. Bernier*, 768 F.2d 1318, 1323 (Fed. Cir. 1985) (quoting *In re Howarth*, 654 F.2d 103, 105 (C.C.P.A. 1981)), *abrogation on other grounds recognized by Kubota v. Shibuya*, 999 F.2d 517 (Fed. Cir. 1993). Otherwise, “patent specifications would turn into production specifications, which they were never intended to be.” *Id.* (quoting *In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962); accord *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (“[I]t is unnecessary to spell out every detail of the invention in the specification . . .”).

In assessing whether “undue experimentation” is required, “[t]he key word is ‘undue, not experimentation.’” *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1336-37 (Fed. Cir. 2005) (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)). “[T]he specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation.” *Id.* at 1337 (citing *Nat’l Recovery Techs., Inc. v.*

*Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196-97 (Fed. Cir. 1999)); *Wands*, 858 F.2d at 736-37 (“Enablement is not precluded by the necessity for some experimentation such as routine screening.”). “That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive.” *DeGeorge*, 768 F.2d at 1323 (quoting *Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984)). “[A] specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.” *In re Borkowski*, 422 F.2d 904, 908 (C.C.P.A. 1970); *see also Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (discussing the *Wands* factors, 858 F.2d at 737).

“[T]he level of disclosure necessary . . . varies according to the scope of the claimed invention.” *CFMT, Inc. v. YieldUp Int’l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003). Later optimization of an invention to satisfy commercial requirements does not indicate that an invention was not enabled as of the priority date. *Id.*

#### **X. BEST MODE**

Determining whether there has been a best mode violation is a two-step process. The first step is to determine whether the inventors had a best mode of practicing the invention as claimed as of the priority date. *High Concrete Structures, Inc. v. New Enter. Stone & Lime Co.*, 377 F.3d 1379, 1382-83 (Fed. Cir. 2004); *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1320 (Fed. Cir. 2002); *Waldemar Link GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558 (Fed. Cir. 1994). If there is not clear and convincing evidence that the inventors had a best mode of practicing the claimed invention, then there can be no violation. *See Bayer AG*, 301 F.3d at 1321; *Young Dental Mfg. Co. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1144 (Fed. Cir. 1997). The second step is to determine whether the best mode was not disclosed in sufficient detail to

allow one of skill in the art to practice the best mode without undue experimentation. *High Concrete Structures*, 377 F.3d at 1382-83; *Bayer AG*, 301 F.3d at 1320; *Young*, 112 F.3d at 1144 (“[T]o satisfy the second inquiry of the best mode test, an inventor need only disclose information about the best mode that would not have been apparent to one of ordinary skill in the art.”); *Young*, 112 F.3d at 1145 (holding no best mode violation where inventor disclosed types of plastic but not specific grades, because it would have been “readily apparent to one of skill in the art to select the particular grade of plastic” given disclosure of the types of plastic; grades were “routine details”). Accordingly, “[t]here can be no best mode violation where a person of ordinary skill would have known the purported best mode through the scientific literature.” *McNeil-PPC, Inc. v. Perrigo Co.*, 516 F. Supp. 2d 238, 257-58 (S.D.N.Y. 2007) (holding publication of feature in foreign patent application prior to issuance of patent satisfied best mode requirement); *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1346 (Fed. Cir. 2000) (holding disclosure of feature in prior art literature satisfied best mode requirement). The best mode for practicing a claim to a composition of matter does not include the method of making the composition or ingredients or precursors used to make the composition unless they have a “material effect on the properties of the claimed invention.” *Bayer*, 301 F.3d at 1321.

## **XI. WRITTEN DESCRIPTION**

Whether there is a violation of the written description requirement depends on whether the patent sufficiently describes the claimed invention to a person of ordinary skill in the art to put a person of ordinary skill in the art in possession of the claimed composition. *See, e.g., Bilstad v. Wakalopulos*, 386 F.3d 1116, 1123 (Fed. Cir. 2004). The patent only needs to describe the invention as recited in the claim sufficient to put a person of ordinary skill in the art in possession of the invention; the recitation need not be a verbatim recitation of the claim. *See Moba, B.V., v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319-20 (Fed. Cir. 2003) (per curiam);

*Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). The description of an invention as including a particular element does not require that the claim explicitly include that element—such an “essential element” test has been explicitly repudiated. *See Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002).

## **XII. RELIEF REQUESTED**

If a court determines that a patent has been infringed by a proposed ANDA product, “the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.” 35 U.S.C. § 271(e)(4)(A); *see also* 21 U.S.C. § 355(j)(5)(B)(iii). In addition, “injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or imported into the United States” of the infringing product. 35 U.S.C. § 271(e)(4)(B).

“The Court in exceptional cases may award reasonable attorney fees to the prevailing party.” 35 U.S.C. § 285. “[M]any types of misconduct that may create an exceptional case for purposes of awarding fees, including inequitable conduct before the PTO, litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement.” *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350 (Fed. Cir. 2004).

“Unless a federal statute, these rules, or a court order provides otherwise, costs—other than attorney’s fees—should be allowed to the prevailing party.” Fed. R. Civ. P. 54(d)(1); *see also* D. Del. L.R. 54(a)(1).

# EXHIBIT 5



**EXHIBIT 5**

**TEVA'S STATEMENT OF ISSUES OF LAW THAT REMAIN TO BE LITIGATED**

**ISSUES ON WHICH TEVA BEARS THE BURDEN OF PROOF**

Teva submits this Statement of Issues of Law that remain to be litigated without waiving prior positions taken by Teva. To the extent that any issues of fact set forth in Teva's Statement of Facts That Remain To Be Litigated may be considered as issues of law, Teva hereby incorporates those issues by reference. Teva also incorporates by reference any portion of Teva's Brief Statement of Intended Proofs to the extent that the Court determines that it raises additional legal issues.

**I. CLAIM CONSTRUCTION**

Claims 1, 2, 8, 9 and 11 of the '517 patent should be construed to mean a diastereomeric mixture of compounds in which there are two or more diastereomers, and a racemate of a single diastereomer. The asserted claims of the '517 patent should be construed not to mean a single enantiomer or a mixture of a single enantiomer and its mirror image, other than as a racemate. The specification of the '517 patent and the prosecution history of the application for the '517 patent and related applications compel this construction. Similarly, claims 2, 4, and 7 of the '942 patent should be construed the same way.

For claims 1, 3, and 5 of the '942 patent, the claim term "substantially free of other enantiomers and stereoisomers," to the extent it can be understood, should be construed to mean that any impurities consisting of "other enantiomers" or "other stereoisomers," if present, are not detectable.

The claims of a patent define the scope of the invention from which the patentee is entitled to exclude others. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

banc). Claim construction begins with a review of the same resources a person of ordinary skill in the art would review in attempting to determine the meaning of claim terms, namely, the patent's specification and prosecution history. *Id.* at 1313.

The starting point for the construction of claim terms is that claim terms are generally given their ordinary and customary meaning. *Phillips*, 415 F.3d at 1312 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Because the meaning of a claim term is often not readily apparent, Courts may look to other sources to determine the meaning of a claim term to a person of ordinary skill in the art. *Id.* at 1314. These sources include the claims themselves, the patent's specification and prosecution history, and extrinsic evidence that is relevant and helpful to the Court. *Id.*

The specification is the primary basis for construing the claims. *Phillips*, 415 F.3d at 1315. In construing claim language, the Court should not read limitations from the specification into the claims. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002). Further, a patentee who, in drafting the specification, discloses but does not claim embodiments of the invention dedicates to the public those disclosed-but-unclaimed embodiments. *Johnson & Johnston Assocs. Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc) (per curiam) (“[W]hen a patent drafter discloses but declines to claim subject matter ... this action dedicates that unclaimed subject matter to the public.”).

Additionally, the Court construing the claim should also consider the patent's prosecution history. *Phillips*, 415 F.3d at 1317. Applicant's statements during the prosecution history can provide important guidance as to the meaning of claim terms, regardless of whether the Examiner relied on those statements during prosecution. *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1462-63 (Fed. Cir. 1998). Statements allegedly made by other parties

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

besides the applicant are irrelevant to the construction of patent claim terms. *Cf. id.* at 1462-63 (“It is the *applicant’s* representations during prosecution that potentially shed light on the construction of the claims, not the representations of a reexamination requester” or alleged infringer.) (emphasis in original) (internal citation omitted). Furthermore, when the same claim term appears in two related patents, the prosecution histories of each of these related patents is relevant to an understanding of the proper construction of the claim term. *Id.* at 1460 n.2; *see also Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004) (even though a patent has already issued, “it is not unsound” to apply a claim interpretation based on the prosecution of a continuation application to that patent); *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1327-28 (Fed. Cir. 2003).

As a part of its claim construction, the Court may also rely on extrinsic evidence. “Extrinsic evidence” consists of “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995)). However, extrinsic evidence is of less value than the intrinsic record (i.e., the patent’s claims, specification, and prosecution history) in determining the proper construction of claim terms. *Id.* (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). While extrinsic evidence such as dictionaries, treatises, and expert testimony may be considered, “conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.” *Id.* at 1318.

There are several reasons why extrinsic evidence is less helpful than intrinsic evidence to the Court construing the claims of a patent. First, because extrinsic evidence is not a part of the patent, it lacks the virtue of being created contemporaneously with patent prosecution for the

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

purpose of explaining claim term meaning. *Id.* Second, unlike the patent's specification, the intended audience of extrinsic evidence may be different from that of the patent, and therefore the extrinsic evidence "may not reflect the understanding of a skilled artisan in the field of the patent." *Id.* Third, extrinsic evidence, especially expert reports and testimony, are created for the purpose of litigation and therefore may be influenced by bias. *Id.* Fourth, because the universe of potential extrinsic evidence is so broad, there is a danger that the parties will pick and choose the evidence they rely on based on their positions, leaving the Court "with the considerable task of filtering the useful extrinsic evidence from the fluff." *Id.* (citation omitted). Fifth, undue reliance on extrinsic evidence may lessen the weight of the intrinsic evidence, which would undermine the public notice function of patents. *Id.* at 1319. Accordingly, the Federal Circuit has explained that extrinsic evidence "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319.

The granting of a Patent Term Extension by the Patent Office is not indicative of the proper construction of a claim. *Abbott Labs. v. Dey, L.P.*, 110 F. Supp. 2d 667, 673 (N.D. Ill. 2000). The granting of a patent term extension does not involve a determination by the Patent Office of a claim term's meaning, "and even if it did, the PTO is not required to interpret a patent's claims in the same manner as courts are required during infringement proceedings...." *Id.* (citing *In re Morris*, 127 F.3d 1048, 1053 (Fed. Cir. 1997)).

U.S. Patent No. 4,990,517 ("The '517 Patent")

1. Whether, in view of the specification and file histories of the '517 patent and related applications, the compounds defined by the preamble and the formula presented in claims 1, 2, 8, 9 and 11 of the '517 patent are for a diastereomeric mixture in which there are two or more diastereomers, and a racemate of a single diastereomer, such that the compounds defined

Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

by the preamble and the formula presented in claims 1, 2, 8, 9, and 11 do not encompass a single enantiomer, or a mixture of a single enantiomer and its mirror image compound, other than as a racemate.

U.S. Patent No. 5,607,942 ("The '942 Patent")

1. Whether, as to claims 1, 3, and 5, in view of the specification and the file histories of the '942 patent and related applications, the term "said compound substantially free of other enantiomers and stereoisomers," to the extent it can be understood, means that any impurities consisting of "other enantiomers" or "other stereoisomers" must be present in an amount below the detection limit for such enantiomers or stereoisomers.

2. Whether, in view of the specification and file histories of the '942 patent and related applications, the compounds defined in the preamble and the formula presented in claims 2, 4, and 7 of the '942 patent are for a diastereomeric mixture in which there are two or more diastereomers, and a racemate of a single diastereomer, such that the compounds defined by the preamble and the formula presented in claims 2, 4, and 7 do not encompass a single enantiomer, or a mixture of a single enantiomer and its mirror image compound, other than as a racemate.

**A. Redefinition Of Claim Terms By The Patentee**

The inventors of the subject matter of the '830 patent acted as their own lexicographers in defining the term "moxifloxacin" to mean a chemical having the structural formula set forth in the specification. The term "moxifloxacin" in claim 1 of the '830 patent thus has this specially defined meaning.

When a patentee provides in the patent's specification a special definition of a claim term, the patentee's definition (or "lexicography") governs with respect to claim construction. *Phillips*, 415 F.3d at 1316 (Fed. Cir. 2005) (en banc). Indicia in the patent specification, such as

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

surrounding the claim term in quotation marks or use of the word "is" following the term in question, provide evidence that the patentee has expressly defined the claim term. *Sinorgchem Co. v. ITC*, --- F.3d ----, No. 2006-1633, 2007 WL 4465270, at \*4 (Fed. Cir. Dec. 21, 2007); *see also Hyperphrase Techs., LLC v. Google, Inc.*, Nos. 2007-1125, 2007-1176, 2007 WL 4509047, at \*3 (Fed. Cir. Dec. 26, 2007) (non-precedential<sup>1</sup>). However, an explicit statement of redefinition is not required for a patentee to act as his own lexicographer. *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1362 (Fed. Cir. 2007).

A patentee is fully entitled to redefine a term in a way which is contrary to the "ordinary and customary meaning" of the term to those of ordinary skill in the art. *Honeywell Int'l*, 493 F.3d at 1361 (Fed. Cir. 2007) ("The conventional meaning of the terms 'heading' and 'bearing' is undisputed. 'Heading' ordinarily refers to the direction in which an object is pointing. 'Bearing' ordinarily refers to the direction from an observer to an object. The specification and prosecution history make clear, however, that the patentees used the term 'heading' in a manner different from its ordinary meaning."). Simply put, if the "specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Sinorgchem*, 2007 WL 4465270, at \*5 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998)). In such a situation, no further inquiry by the Court into the intrinsic or extrinsic evidence is required.

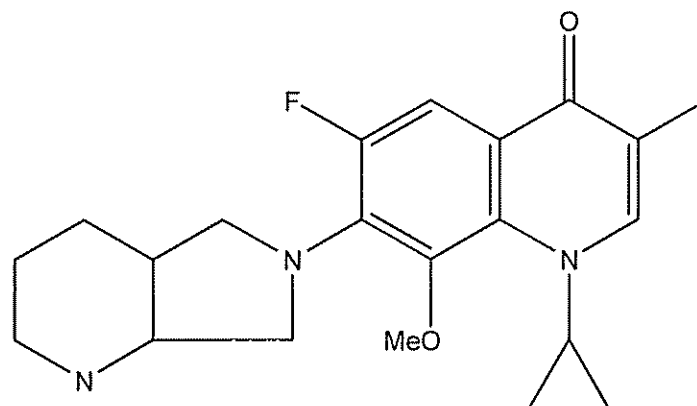
U.S. Patent No. 6,716,830

1. Whether the term moxifloxacin in claim 1 of the '830 patent means a compound of the formula:

---

<sup>1</sup> Effective December 1, 2007, under Federal Circuit Rule 32.1(c), "Parties are not prohibited or restricted from citing nonprecedential dispositions issued after January 1, 2007. "

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated



## II. NONINFRINGEMENT

### A. Infringement Under The Doctrine Of Equivalents

Plaintiffs are estopped from claiming that Teva's moxifloxacin hydrochloride products infringe the claims of the '517 patent and the claims of the '942 patent, in view of the prosecution histories of their applications and related applications.

The "doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 117 S. Ct. 1040, 1049 (1997). The reason for this rule is grounded in fairness to the public: if the range of "equivalents" is unclear, then competitors and the public will be unable to determine what is a permitted alternative to a patented invention. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1835 (2002). The prosecution history of a patent application may be relied on by competitors of the patentee, and Courts asked to rule on infringement, to obtain guidance as to the scope of the claim terms, as the prosecution history provides the patentee with an opportunity to further clarify the scope of his or her invention. *Id.* Accordingly, "prosecution history estoppel" prevents a patentee from capturing, through the doctrine of equivalents, claim scope which he has disclaimed during prosecution. *See id.* at 1839 ("Where the original application once embraced the purported equivalent but the patentee narrowed his claims to



## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question.”).

Prosecution history estoppel operates to restrict the range of “equivalents” when the patentee makes an amendment during prosecution which narrows the patent’s scope. *Festo*, 122 S. Ct. at 1840. A narrowing amendment results in prosecution history estoppel if the amendment is made to satisfy *any* requirement of the patent laws. *Id.* at 1839. Because the patentee is in the best position to explain his invention, any narrowing amendment is presumed to be a disclaimer of the territory between the original and amended claims. *Id.* at 1842. Furthermore, when the patentee is unable to explain why an amendment was made, prosecution history estoppel bars the application of the doctrine of equivalents to that element. *Id.* (quoting *Warner-Jenkinson*, 117 S. Ct. at 1040).

Prosecution history estoppel can also occur when the applicant makes an argument to the Examiner which surrenders the scope of the claims (“argument-based estoppel”). *Conoco, Inc. v. Energy & Env’t Int’l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006) (citation omitted). Arguments which show a clear and unmistakable surrender of claim scope operate to restrict the claims. *Id.* At 1364 (quoting *Deering Precision Instruments, LLC v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1326 (Fed. Cir. 2003)).

Consistent with the requirement that the doctrine of equivalents must be applied in an element-by-element basis, the ‘all elements rule’ requires that the doctrine of equivalents not be applied if doing so would vitiate, or read out of the claim, an entire claim limitation. *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) (citing *Warner-Jenkinson*, 117 S. Ct. at 1049); *see also Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321 (Fed. Cir. 2007).



## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

**III. U.S. PATENT NO. 5,607,942****A. Invalidity****i. Asserted Claims 1, 3, And 5 Of The '942 Patent Are Invalid For Indefiniteness**

Asserted claims 1, 3, and 5 of the '942 patent are indefinite since neither the specification, prosecution history nor prior art give any indication as to the meaning of the term "substantially free of other enantiomers and stereoisomers." Further, there is nothing to clarify the scope of this claim term.

Section 112, Title 35 of the U.S. Code requires that a patent's "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. The inquiry in determining if a claim is indefinite is whether those skilled in the art would understand what the claim covers. *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1217 (Fed. Cir. 1991). A claim is properly held invalid when its meaning is in doubt. *Id.* at 1218. In short, a claim is indefinite when a person of ordinary skill in the art could not determine the claim's bounds, that is, when the claim is "insolubly ambiguous." *Halliburton Energy Services, Inc. v. M-I LLC*, --- F.3d. ----, No. 2007-1149, 2008 WL 216294, at \*3 (Fed. Cir. 2008).

The definiteness requirement serves to ensure that the public has adequate notification of the scope of the patentee's right to exclude. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005) (citation omitted). The use of an ambiguous term in a claim leads to the invalidity of the claim. See *In re Corkill*, 111 F.2d 1496, 1500-1501 (Fed. Cir. 1985) (affirming indefiniteness of patent claim, where claim failed to clearly circumscribe an acceptable range of particle diameters). During litigation, the determination of the indefiniteness of patent claims grows out of the Court's function in construing the language of the claims. See

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

*Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1371 (Fed. Cir. 2004) (“In ruling on a claim of patent indefiniteness, a court must determine whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.”)

If there is no indication in the specification, prosecution history, or prior art of what range is covered by a word of degree, such as “about,” and expert testimony as to the meaning of the word of degree does not clarify the question, a claim containing a word of degree is rightly held to be invalid. *Amgen*, 927 F.2d at 1218; *see also Halliburton*, 2008 WL 216294, at \*4 (stating that neither the patentee’s proposed definition or any other possible construction resolves the ambiguity in the scope of the term “fragile gel.”). An argument by the patentee that a claim limitation merely means “adequate for the circumstances” is not helpful in resolving the limitation’s ambiguity. *Halliburton*, 2008 WL 216294, at \*7.

1. Whether the claim term “substantially free of other enantiomers and stereoisomers” in claims 1, 3, and 5 of the ‘942 patent is indefinite and, therefore, claims 1, 3, and 5 are invalid under 35 U.S.C. § 112, second paragraph.

**ii. The Asserted Claims Of The ‘942 Patent Are Invalid For Double Patenting**

The asserted claims of the ‘942 patent are invalid under 35 U.S.C. § 121 because the claims are not consonant with the restriction requirement entered in the application that became the ‘517 patent.

The doctrine of double patenting advances the public policy of prohibiting a patentee from receiving multiple patents for the same invention. There are two forms of the prohibition on double patenting: statutory double patenting and judicially-created, non-statutory double patenting. *Bayer AG v. Dr. Reddy’s Labs., Ltd.*, 518 F. Supp. 2d 617, 638 (D. Del. 2007). Non-statutory double patenting is sometimes referred to as “obviousness-type double patenting.” *Id.*

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

The Federal Circuit has noted that the use of the word "obviousness" in this phrase is unfortunate, particularly in situations where a divisional application is actually directed to (though in different language) the same invention as the elected claims in the parent application.

*Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 687 (Fed. Cir. 1990).

The third sentence of 35 U.S.C. § 121 states:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the Courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

According to the Patent Office's Manual of Patent Examining Procedure, restriction "is the practice of requiring an applicant to elect a single claimed invention (e.g., a combination or subcombination invention, a product or process invention, a species within a genus) for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application." Manual of Patent Examining Procedure, § 802.02 (Eighth Ed., revision 6, September 2007).

However, the protection provided by the third sentence of § 121 only applies to a divisional application when the divisional application is filed "as a result" of a restriction requirement. *Gerber*, 916 F.2d 687. Thus, in order to obtain the benefits of § 121, the inventors of the second patent must have brought their later claims within the purview of the statute by limiting the claims in the divisional application to the non-elected invention or inventions. *Id.* at 688. Accordingly, § 121 does not protect the claims of a second patent from a finding of invalidity for double patenting if the claims of the second patent are not "consonant" with the restriction requirement entered during the prosecution of the earlier, related patent. *See id.*

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

“Consonance requires that the line of demarcation between the ‘independent and distinct inventions’ that prompted the restriction requirement be maintained.” *Id.* If that line is crossed, the protections of § 121 do not apply to the divisional application. *Id.* Because § 121 could potentially operate to extend the patent term for inventions which are not patentably distinct, the Federal Circuit “applies a strict test for application of § 121.” *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003). Section 121 applies only when the restriction requirement is clear and detailed enough to allow for a determination that the divisional application’s claims are consonant with the restriction requirement. *Id.*

Consistent with the judicially-created nature of non-statutory double patenting, the Federal Circuit has also explicitly enumerated the ways in which the non-statutory double patenting analysis under 35 U.S.C. § 121 is distinct from the obviousness analysis under 35 U.S.C. § 103. These distinctions include:

1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;
2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;
3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.

*Geneva Pharms.*, 349 F.3d at 1377 n.1.

When a claim limitation is presented as a Markush group, the applicant is deemed to have “made a representation that for the purpose of the claimed invention the elements of the group are equivalents.” *In re Skoll*, 523 F.2d 1392, 1397 (C.C.P.A. 1975).

1. Whether claims 1, 3, and 5 of the ‘942 patent are invalid for non-statutory double patenting per *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir.

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

2003). Teva does *not* base its double patenting contention on *In re Schneller*, 397 F.2d 350 (C.C.P.A. 1968).

2. Whether claims 2, 4, and 7 of the '942 patent are invalid for non-statutory double patenting per *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003). Teva does *not* base its double patenting contention on *In re Schneller*, 397 F.2d 350 (C.C.P.A. 1968).

## **B. Unenforceability**

### **i. The '942 Patent Is Unenforceable Due To Inequitable Conduct**

Drs. Bremm and Petersen of Bayer acted inequitably during the prosecution of the application for the '942 patent in their submission of declarations by Dr. Bremm to convince the Patent Office to allow the patent application.

Both patent applicants and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the Patent Office. *Praxair, Inc. v. ATMI, Inc.*, 489 F. Supp. 2d 387, 392 (D. Del. 2007) (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a)). This duty of candor also extends to any other individual who is associated with the prosecution of the patent application. 37 C.F.R. § 1.56(a). "A breach of this duty constitutes inequitable conduct." *Praxair*, 489 F. Supp. 2d at 392 (citing *Molins*, 48 F.3d at 1178)). If it is established that someone owing a duty of candor to the Patent Office acted inequitably with respect to one claim, then the entire patent application is unenforceable. *Id.* at 392 (citing *Kingsdown Med. Consultants v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988)).

"In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to patentability of the invention; (2) the applicant had knowledge of the existence and materiality

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

of the information; and (3) the applicant intended to deceive the PTO.” *Praxair*, 489 F. Supp. 2d at 393. A two-step process is thus involved. First, the Court must determine whether the threshold level of materiality and intent is met; if so, the Court then determines if the person owing a duty of candor acted with the requisite intent to mislead the Patent Office. *See id.* “Smoking gun” evidence is not required to support a finding of intent to deceive. *Id.* Rather, an inference of intent is warranted where a patent applicant knew or should have known that the withheld information would be material to the Patent Examiner’s consideration of the patent application. *Id.*

Once materiality and intent to deceive have been shown, the Court must weigh them to determine whether the balance tips in favor of a conclusion of inequitable conduct. *Praxair*, 489 F. Supp. 2d at 393 (citing *N.V. Akzo v. E.I. DuPont de Nemours*, 810 F.2d 1148, 1153 (Fed. Cir. 1987)). This balance occurs on a sliding scale: “[t]he showing of intent can be proportionally less when balanced against high materiality.” *Id.* For example, when a person owing a duty of candor to the Patent Office knows or should know that embodiments within the scope of a pending claim have exhibited poor results, and yet the person owing the duty of candor does not inform the Patent Office of these poor results, the Federal Circuit has held that a finding of inequitable conduct is proper. *Bristol-Myers Squibb Co. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234-35, 1239-40 (Fed. Cir. 2003); *see also Monsanto Co. v. Bayer Bioscience N.V.*, --- F.3d ---, No. 2007-1109, 2008 WL 200027 (Fed. Cir. 2008) (holding that failure to disclose to the Patent Office notes taken by a Bayer scientist which contradicted non-obviousness arguments made by applicant amounted to inequitable conduct).

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

Materiality

In 1992, the Patent Office amended 37 C.F.R. § 1.56, which contains a standard for determining whether information is material to a patent application. *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006). This amendment, in addition to a series of Court decisions, resulted in five possible standards for determining whether information is material:

- The “reasonable examiner” standard found in the pre-1992 version of 37 C.F.R. § 1.56(b), whereby information is material “where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent;”
- The arguably narrower standard found in the current version of 37 C.F.R. § 1.56(b) (modified in 1992), whereby information is material if it (a) establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim or (b) refutes, or is inconsistent with, a position the applicant takes in either opposing an argument of unpatentability relied on by the Patent Office or in asserting an argument of patentability;
- The objective “but for” standard, where the misrepresentation was so material that the patent should not have issued;
- The subjective “but for” test, where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; or
- The “but it may have” standard, where the misrepresentation may have influenced the patent examiner in the course of prosecution.



## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

*Digital Control*, 437 F.3d at 1314-16. The Federal Circuit has determined that information is material to patentability if that information meets *any* of the five standards articulated above. *Id.* at 1316.

The materiality component of the inequitable conduct analysis can be met by an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information. *Refac Int'l, Ltd. v. Lotus Devel. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996). Affidavits submitted to the Patent Office are considered to be inherently material. *Id.* Furthermore, a determination of materiality should not be based on the subjective beliefs of the patentee. *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007). In particular, when testing has occurred, a "reasonable examiner would certainly want to consider test data that is directly related to an important issue of patentability, along with the applicant's interpretation of that data." *Id.*

### Intent

Intent must generally be inferred, based on the facts and circumstances surrounding the applicant's overall conduct. *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1345 (Fed. Cir. 2007) (citation omitted). The level of intent required to find inequitable conduct is less than the level of intent required to find that common law fraud has occurred. *See Dippin' Dots*, 476 F.3d at 1346. When a person owing a duty of candor to the Patent Office knows or should know that information would be material to the Examiner, but nonetheless withholds that information, arguments of "good faith" do not negate an intent to manipulate the evidence. *Cargill*, 476 F.3d at 1368. "Indeed, self serving manipulation of highly material evidence can hardly be called 'good faith.'" *Id.* (citation omitted); *see also Dippin' Dots*, 476 F.3d at 1346 ("While DDI wholly neglected to disclose the Festival Market sales to the PTO, it enthusiastically touted sales



## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

made after the critical date as evidence of the commercial appeal of its process. That combination of action and omission permits an inference of the minimum, threshold level of intent required for inequitable conduct.”).

#### **IV. INVALIDITY OF U.S. PATENT NO. 6,716,830**

##### **A. Claim 1 Of The ‘830 Patent Is Anticipated By The ‘942 Patent**

Assuming that claim 1 of the ‘830 patent is construed as Plaintiffs contend, claim 1 of the ‘830 patent is anticipated by the prior art ‘942 patent. Each and every element of claim 1 of the ‘830 patent is disclosed in the ‘942 patent.

A patent claim is anticipated, and therefore invalid, if every limitation in the claim is found, either explicitly or inherently, in a single prior art reference. *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1381 (Fed. Cir. 2006). The scope of the prior art is defined by the various subparts of 35 U.S.C. 102; that is, if a reference falls within the scope of any of the subparts of § 102, that reference may anticipate, and thus render invalid, the claim at issue. For example, 35 U.S.C. § 102(a) states that a person is not entitled to a patent if “the invention was known or used by another in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent”.

Next, section 102(b) states that a person is not entitled to a patent if “the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States”. 35 U.S.C. § 102(b). Because of the numerous ways in which a reference may be disseminated to the public, the Federal Circuit has referred to “public accessibility” as the touchstone in determining whether a reference can constitute a printed publication bar under 35 U.S.C. § 102(b). *SRI Int’l, Inc. v. Internet Sec. Sys., Inc.*, --- F.3d ----, No. 2007-1065, 2008 WL 68679, at \*6 (Fed. Cir. 2008) (quoting *In re Hall*, 781 F.2d 897, 989-99 (Fed. Cir.

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

1986)). A reference is "publicly accessible" if the document has been disseminated or otherwise made available, to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence can locate it and recognize and comprehend from it the essentials of the claimed invention without the need for further research or experimentation.

*Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006).

A reference may be anticipatory even though one or more of the elements it discloses appears in a longer list without special emphasis. See *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005). "[T]he disclosure is prior art to the extent of its enabling disclosure." *Id.* (citation omitted).

Where a patent claim element is directed to a range of values, that element is anticipated if a single point in that range is disclosed in a prior art reference; the prior art reference need not disclose the entire range in order to be anticipatory. *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 781 (Fed. Cir. 1985) ("The second item shows a titanium base alloy containing 0.25% by weight Mo and 0.75% Ni and this is squarely within the ranges of 0.2-0.4% Mo and 0.6-0.9% Ni of claims 1 and 2. As to that disclosed alloy of the prior art, there can be no question that claims 1 and 2 read on it and would be infringed by anyone making, using, or selling it. Therefore, *the statute prohibits* a patent containing them.") (emphasis in original); see also *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999) ("[W]hen a patent claims a chemical composition in terms of ranges of elements, any prior art reference that falls within each of the ranges anticipates the claim."). This is consistent with the Federal Circuit's determination that a patent provides an adequate written description of a range of values, even without separately listing the values within that range, when providing the range would show a person of ordinary skill in the art that the patentee possessed the claimed invention at the time of

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

filing. *See Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997-98 (Fed. Cir. 2000).

For a prior art reference to anticipate the claim, the reference must enable one skilled in the art to make or use the claimed subject matter. *Impax*, 468 F.3d at 1381. Whether a prior art patent is “enabling” in the anticipation context is different, however, than whether a prior art patent is “enabled” under 35 U.S.C. § 112 in that, unlike under § 112, an anticipatory reference need not have a demonstrated utility. *Id.* at 1381-82. Furthermore, when an accused infringer asserts that a prior art patent anticipates a patent claim, the accused infringer is entitled to a presumption that the allegedly anticipating material is enabled. *Id.* at 1382.

**B. Claim 1 Of The ‘830 Patent Is Obvious In Light Of The Prior Art**

Assuming that claim 1 of the ‘830 patent is construed as Plaintiffs contend, claim 1 of the ‘830 patent would have been obvious to one of ordinary skill in the art at the time the invention was filed in view of the prior art. The alleged secondary considerations are insufficient to rebut the strong *prima facie* case of obviousness, and they are not probative of nonobviousness since they are not commensurate in scope with claim 1.

Under Section 103(a), Title 35 of the U.S. Code, a patent claim is invalid “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” “Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Graham v. John Deere Co. of Kansas City*, 86 S. Ct. 684, 694 (1966). If, after conducting this analysis, a Court concludes that the claimed subject matter was obvious, then the claim is invalid. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). Because “progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.” *Id.* at 1746 (citing U.S. Const., Art. I, § 8, cl. 8). As a part of the obviousness inquiry, a Court is not required to find that the prior art provides some motivation or suggestion to combine the prior art teachings as a predicate to a finding of obviousness. *Id.* at 1739.

As used in § 103, the term “prior art” refers at least to the material identified in 35 U.S.C. § 102. *Riverwood Int’l Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1354 (Fed. Cir. 2003) (citing *In re Werthiem*, 646 F.2d 527, 532 (C.C.P.A. 1981)). The prior art also includes the file histories of issued patents. *See Bruckelmyer*, 445 F.3d at 1377-80.

The Supreme Court has long “held that a ‘patent for a combination which only unites old elements with no change in their respective functions ... obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful [people].’” *KSR*, 127 S. Ct. at 1739 (quoting *Great Atl. & Pacific Tea Co. v. Supermarket Equip. Corp.*, 71 S. Ct. 127 (1950)). Similarly, when a patent claim which simply arranges old elements, where each performs a known function and yields no more than one would expect from the arrangement, “the combination is obvious.” *Id.* at 1740. Simply put, as part of the analysis under § 103, a Court “must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* In doing so, the Court can

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

consider the inferences and creative steps that a person of ordinary skill in the art would employ, and “need not seek out precise teachings directed to the specific subject matter of the challenged claim.” *Id.* at 1741.

Accordingly, any need or problem known in the art at the time of invention and addressed by the patent can provide the reason for combining elements in the claimed manner. *KSR*, 127 S. Ct. at 1742. It follows, then, that scientific literature is not the only source of reasons for combining elements in a certain manner. Rather, other information, such as market demand, may provide the drive to combine elements in a particular way. *Id.* at 1741. As the Supreme Court stated, the “person of ordinary skill is also a person of ordinary creativity, not an automaton.” *Id.* at 1742.

The scope of possible solutions to a problem also has a bearing on whether a claim is obvious. “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *KSR*, 127 S. Ct. at 1742. For example, where a claim is directed to a topical pharmaceutical composition containing a fluoroquinolone active agent, and the prior art discloses a topical pharmaceutical composition containing another fluoroquinolone active agent, the Federal Circuit has held that the claim is obvious. *See Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (otic composition of ofloxacin was obvious over prior art otic composition of ciprofloxacin).

It is not necessary for the full scope of a claim to be obvious for that claim to be invalid under 35 U.S.C. § 103; rather, “[i]f the claim extends to what is obvious, it is invalid under

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

§ 103.” *KSR*, 127 S. Ct. at 1742. When a claimed range overlaps or lies within ranges disclosed by the prior art, a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976); *In re Woodruff*, 919 F.2d 1575 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-71 (Fed. Cir. 1997). A difference in concentration or temperature generally will not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating such concentration or temperature is critical.<sup>2</sup> *See, e.g., Woodruff*, 919 F.2d at 1578 (When the difference between the prior art and the claim is some range within the scope of the claim, “the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range.”) (emphasis in original). If the prior art discloses the general conditions in a claim, discovering the optimum or workable ranges through routine experimentation is not inventive. *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955). A purported showing of unexpected results must be backed by factual evidence; mere argument or conclusory statements in the specification are insufficient. *In re Geisler*, 116 F.3d at 1470 (quoting *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1994)).

Whether a claim is obvious is viewed through the eyes of a person having ordinary skill in the art. “Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) types of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Daiichi*, 501 F.3d at 1256 (citation omitted). A person having ordinary skill in the art is presumed to have access to, and knowledge of, all that which qualifies as “prior art” in the field to which the patent pertains. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1452

---

<sup>2</sup> *See also* Manual of Patent Examining Procedure, § 2144.05 (Eight Ed., revision 6, September 2007).

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

(Fed. Cir. 1984); *In re Antle*, 444 F.2d 1168, 1171-72 (C.C.P.A. 1971); *see also In re Winslow*, 365 F.2d 1017, 1020 (C.C.P.A. 1966). This includes file histories of issued patents and of published patent applications. *See Bruckelmyer*, 445 F.3d at 1377-80.

Even where a patentee has shown "substantial evidence" of objective evidence of patentability (i.e., secondary considerations), such as commercial success, praise, and long felt need, that showing is inadequate to overcome a final conclusion that a claim is obvious if the defendant's *prima facie* case of obviousness is sufficiently compelling. *See Leapfrog Enters, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1484 (Fed. Cir. 1997) (showing of unexpected results and commercial success of claimed ibuprofen and pseudoephedrine combination in single tablet form, while supported by substantial evidence, held not to overcome strong *prima facie* showing of obviousness).

Furthermore, objective evidence of non-obviousness "must be commensurate in scope with the claims which the evidence is offered to support." *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium). Objective evidence which is not commensurate with the scope of the claim is thus entitled to little or no weight in the Court's obviousness analysis. *See also In re Grasselli*, 713 F.2d 731, 741 (Fed. Cir. 1983) (claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The Court held this evidence insufficient to rebut the *prima facie* case because experiments limited to sodium were not commensurate in scope with the claims).



## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

Furthermore, in order to be commensurate in scope with the claims, objective evidence, such as commercial success, must be due to claimed features, not due to unclaimed features. *Joy Techs., Inc. v. Manbeck*, 751 F. Supp. 225, 229 (D.D.C. 1990), *aff'd*, 959 F.2d 226, 228 (Fed. Cir. 1992) (features responsible for commercial success were recited only in allowed dependent claims, and therefore the evidence of commercial success was not commensurate in scope with the broad claims at issue); *In re Tiffin*, 448 F.2d 791 (C.C.P.A. 1971) (evidence showing commercial success of thermoplastic "cups" used in vending machines was not commensurate in scope with claimed directed to thermoplastic foam "containers" broadly).

To be pertinent to the issue of nonobviousness, the commercial success of devices falling within the claims of the patent must flow from the functions and advantages disclosed or inherent in the description in the specification. The success of an embodiment within the claims may not be attributable to improvements or modifications made by others. *See In re Vamco Mach. & Tool, Inc.*, 752 F.2d 1564, 1577 (Fed. Cir. 1985).

1. Assuming claim 1 of the '830 patent is construed as Plaintiffs contend, whether claim 1 of the '830 patent would have been obvious to one of ordinary skill in the pharmaceutical art as of the time the invention was made in 1998.

### **C. The '830 Patent Is Invalid For Lack Of Enablement**

Assuming that claim 1 of the '830 patent is construed as Plaintiffs contend, the specification of the '830 patent does not enable the composition claimed in claim 1 if the persons of ordinary skill in the art are the persons identified by Alcon's experts.

The first paragraph of 35 U.S.C. § 112 requires that a patent be enabled for it to be valid. More particularly, a patent's "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact



## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....” According to the Federal Circuit, the specification must enable one of ordinary skill in the art to practice the full scope of the invention; this requirement is “part of the *quid pro quo* of the patent bargain.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007) (citation and quotation omitted). This requirement ensures that the public’s knowledge is enriched by the teachings in the patent to a degree at least as broad as the scope of the claims. *Sitrick v. Dreamworks, LLC. et al.*, --- F.3d ---, No. 2007-1174, 2008 WL 269443, at \*4 (Fed. Cir. 2008) (quoting *Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999)).

Although the term “undue experimentation” does not appear in the statute, enablement “requires that the specification teach those in the art to make and use the invention without undue experimentation.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Factors to be considered in determining whether a disclosure would require undue experimentation include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.* Opinions offered by experts who are not skilled in the relevant art and which are conclusory and unsupported by actual information are insufficient to show that a claim is enabled. *See Sitrick*, 2008 WL 269443, at \*6 (stating that such opinions do not raised a triable issue of fact). Where a claim is broad enough to cover multiple categories of embodiments, the patent must enable each category. *Id.* at \*5 (“Because the asserted claims are broad enough to cover both movies and video games, the patents must enable both embodiments.”).

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

1. If the definition of ordinary skill in the art proffered by Alcon is accepted by the Court, whether claim 1 of the '830 patent is sufficiently enabled such that each person of ordinary skill in the art identified by Alcon's experts would be able to practice the invention of claim 1 of the '830 patent without undue experimentation.

**D. The '830 Patent Is Invalid For Failure To Comply With The Best Mode Requirement**

Assuming claim 1 of the '830 patent is construed as Plaintiffs contend, the '830 patent is invalid because the inventors had a best mode of making and using their invention – the use of moxifloxacin hydrochloride – but they did not disclose their best mode in the '830 patent.

The first paragraph of 35 U.S.C. § 112 requires that a patent's specification "shall set forth the best mode contemplated by the inventor of carrying out his invention." The essence of the best mode requirement is that it "requires an inventor to disclose the best mode *contemplated by him*, as of the time he executes the application, of carrying out his invention." *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 926 (Fed. Cir. 1990) (emphasis in original) (quotation and citations omitted). The purpose of the best mode requirement is to prevent inventors from applying for patent protection while at the same time concealing their preferred embodiments from the public. *Id.* Whether the best mode requirement has been complied with is a question of fact. *Id.* at 928.

The best mode analysis has two prongs. *Chemcast*, 913 F.2d at 927. "The first is whether, at the time the inventor filed his patent application, he knew of a mode of practicing his claimed invention that he considered to be better than any other. This part of the inquiry is wholly subjective, and resolves whether the inventor must disclose any facts in addition to those sufficient for enablement." *Id.* at 927-28.

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

The second part of the analysis compares what the inventor knew with what he disclosed—“is the disclosure adequate to enable one skilled in the art to practice the best mode or, in other words, has the inventor ‘concealed’ his preferred mode from the ‘public’? Assessing the *adequacy* of the disclosure, as opposed to its *necessity*, is largely an objective inquiry that depends upon the scope of the claimed invention and the level of skill in the art.” *Id.* at 928 (emphasis in original).

Thus, “where the inventor has failed to disclose the only mode he ever contemplated of carrying out his invention, the best mode requirement is violated.” *Id.* at 930 (citations omitted).

The question of whether an undisclosed best mode was nonetheless enabled is irrelevant to the best mode inquiry. *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1314 (Fed. Cir. 2002) (“Because of the subjective nature of the best mode inquiry, the best mode disclosure requirement—unlike enablement—cannot be met by mere reference to the knowledge of one of skill in the art. The reason is pragmatic. It is unreasonable if not impossible to require the ordinary artisan to peer into the inventor’s mind to discover his or her idiosyncratic preferences as of the filing date.”). Rather, *actual disclosure* of the inventor’s best mode is required, whether it is otherwise enabled or not. *See id.*

**E. The ‘830 Patent Is Invalid For Failure To Provide An Adequate Written Description**

Assuming claim 1 of the ‘830 patent is construed as Plaintiffs contend, claim 1 of the ‘830 patent is invalid under 35 U.S.C. § 112, first paragraph, for failing to provide a written description of the invention. The specification states that a preservative is required, yet claim 1 does not require a preservative.

Section 112, Title 35 of the U.S. Code requires that a patent’s “specification shall contain a written description of the invention....” The “written description” requirement contained in

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

§ 112 is a separate and distinct requirement from the enablement requirement of § 112. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

The reason for a separate written description requirement is based partly on public policy considerations. The written description requirement guards against overreaching by the inventor in that it requires that the invention be described in enough detail to determine if future claims are within the original creation. *Vas-Cath*, 935 F.2d at 1561 (citation omitted). The written description requirement is broader than simply a description of how to “make and use” the invention; rather, the inventor must convey to those skilled in the art that, as of the filing date, the inventor was in possession of the claimed invention. *Id.* at 1563-64.

The Federal Circuit has noted that the analysis of whether a patent complies with the written description requirement is a highly fact-specific inquiry. *Vas-Cath*, 935 F.2d at 1562. Accordingly, “the precedential value of cases in this area is extremely limited.” *Id.* (citation omitted). Nevertheless, the Federal Circuit has articulated a general standard against which compliance with the written description requirement is to be determined: a description must clearly allow persons of ordinary skill in the art to recognize that the applicant invented what is claimed. *Id.* at 1563 (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). Compliance with the written description requirement is therefore tied to claim construction.

One way in which a patent may fail to comply with the written description requirement is by claiming more than is described in the patent's specification; that is, “the scope of the right to exclude may be limited by a narrow disclosure.” *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998). As such, to avoid violation of the written description requirement, claims may be no broader than the supporting disclosure. *Id.* at 1480. There is no requirement that a claim must be construed in such a manner that it includes all examples listed

## Exhibit 5: Teva's Statement Of Issues Of Law That Remain To Be Litigated

in the patent's specification. *Sinorgchem Co. v. ITC*, --- F.3d ----, No. 2006-1633, 2007 WL 4465270, at \*6 (Fed. Cir. 2007) (noting that "we have previously interpreted claims to exclude embodiments where those embodiments are inconsistent with unambiguous language in the patent's specification or prosecution history.") (citations omitted).

1. Whether claim 1 of the '830 patent is broader than the supporting disclosure because claim 1 does not contain a limitation requiring a preservative separate from moxifloxacin, such that the written description does not convey that the inventors of the '830 patent were in possession of the invention of claim 1 as of the filing date of the '830 patent.

## V. EXCEPTIONAL CASE

This case is exceptional because the '942 patent was procured by inequitable conduct and because Alcon is unjustified in asserting its infringement claim of the '830 patent.

Under § 285, Title 35 of the U.S. Code, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." "The prevailing party may prove the existence of an exceptional case by showing: inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement. *Brasselar, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001); *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348, 1355 (Fed. Cir. 2005). Clear and convincing evidence is required to support a finding that a case is "exceptional." *See, e.g., Brasselar*, 267 F.3d at 1378-1379.

# EXHIBIT 6

PLAINTIFFS BAYER HEALTHCARE AG, BAYER PHARMACEUTICALS CORP., ALCON, INC. AND ALCON MANUFACTURING LTD.'S (ALCON RESEARCH, LTD.'S)  
PRELIMINARY TRIAL EXHIBIT LIST

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0001	2/5/1991	Certified Copy of USPN 4,990,517	BT002-000001-000059	PDX 001**; DDX 001**	None
PTX-0002		Certified Copy of the Prosecution History of USPN 4,990,517	BT002-000061-001450		None
PTX-0003	3/4/1997	Certified Copy of USPN 5,607,942	BT002-001451-001504	PDX 003**; PDX 105**	None
PTX-0004		Certified Copy of the Prosecution History of USPN 5,607,942	BT002-001505-002263		None

<sup>1</sup> By setting forth these objections to the documents on Plaintiffs' Preliminary Trial Exhibit List, Teva does not concede that the descriptions of the documents on Plaintiffs' list are necessarily accurate. Teva reserves its right to object further to documents on or added to this list on any basis that depends upon how a document is introduced, for what purpose a document is introduced, and what portion of a document is introduced. To the extent that the Court sustains any of Plaintiffs' objections to the introduction of an exhibit on Teva's Trial Exhibit List based on Plaintiffs' contention of untimely production, Teva reserves the right to object to any exhibit on Plaintiffs' Preliminary Trial Exhibit List that was not timely produced.



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0005	4/6/2004	Certified Copy of USPN 6,716,830	BA001-000009-000016	PDX 005**; PDX 103**	None
PTX-0006		Certified Copy of the Prosecution History of USPN 6,716,830	BA001-001565-003053		None
PTX-0007	4/9/2007	Notice of Deposition of Teva Pursuant to Fed. R. Civ. P. 30(b)(6)		PDX 007	None
PTX-0008	7/17/2007	Stipulation and Order Regarding Documents Produced by Dr. Reddy			None
PTX-0009	7/24/2007	Stipulation and Order Regarding Infringement			None
PTX-0010	7/21/2005	Teva (IL) Requests for Development of Microbiological Method and Study	T005247-005264	PDX 010	Highly Confidential (object to use in open Court)
PTX-0011		ANDA 78-073 Section IV: Comparison of Generic Drug v. Reference Listed Drug and Rx/OTC Statement	T000028-000031	PDX 011	Highly Confidential (object to use in open Court)
PTX-0012		ANDA 78-073 Section V.3: LABELING: Labeling Comparison	T000059-000073	PDX 012	Highly Confidential (object to use in open Court)
PTX-0013	2/2006	Moxifloxacin HCl Ophthalmic Solution 0.5% Pharmaceutical Development Report	T005408-005450	PDX 013	Highly Confidential (object to use in open Court)



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0014		Patent File LeA 26 108-USA-3CIP	RT001-020935-021193		None
PTX-0015	10/25/2007	Judgement, <i>Bayer v. Dr. Reddy's</i> , Case No. 04-179-SLR (D. Del.)	BT003-0000001-0000002		FRE 401/402/403 (irrelevant)
PTX-0016	3/7/2005; 6/27/2005	Assignment of and Recordation of Assignment of USPN 4,990,517 and USPN 5,607,942 from Bayer AG to Bayer HealthCare AG	BL021-000165-166; BL021-000168-000175		None
PTX-0017	1/20/2004	DRL Technical Package for Moxifloxacin HCl	T007881-007965	PDX 017	Highly Confidential (object to use in open Court)
PTX-0018	12/21/2005	ANDA 78-073 Section VIII.1: Raw Material Controls: Active Ingredients	T000107-000177	PDX 018	Highly Confidential (object to use in open Court)
PTX-0019	9/30/1998	US Provisional Application 60/102,504, Cagle et al., <i>Antibiotic Compositions for Treatment of the Eye, Ear and Nose</i> (Alcon)	AL002-002246-002257; AL002-002259		None
PTX-0020		Kadosh Patent File	T005279-005307	PDX 020	Highly Confidential (object to use in open Court)
PTX-0021		Sections Manual of Patent Examining Procedure, identifying revisions	RT001-014390-014419		FRE 401/402/403 (irrelevant; not produced)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0022	5/19/1988	Manual of Patent Examining Procedure: Chapter 800 (5th ed., 8th rev.)	DRLMOX 041664-041692		FRE 401/402/403 (irrelevant; not produced)
PTX-0023		IMS Market Data for Ciloxan, Vigamox and Tobrex over the period 7/2000 through 6/2003	T001477-001485	PDX 023	Highly Confidential (object to use in open Court)
PTX-0024	2006	Hsu et al., <i>Characterization of Antimicrobial Resistance Patterns and Class I Integrons Among Escheria coli and Salmonella enterica serovar Choleraesuis Strains Isolated from Humans and Swine in Taiwan</i> , Inter. J. of Antimicro. Agents 27:383-91 (2006)	BL021-000150-000158		FRCP 34 / FRE 403 (document not produced)
PTX-0025	9/30/1998	US Provisional Application 60/102,506, Cagle et al., <i>Antibiotic Compositions for Treatment of the Eye, Ear and Nose</i> (Alcon)	AL002-002287-002300; AL002-002302		None
PTX-0026		Pipeline Product Profile for Moxifloxacin Ophthalmic Solution	T001572	PDX 026	Highly Confidential (object to use in open Court)
PTX-0027	9/29/1999	PCT Application PCT/US99/22622, Cagle et al., <i>Antibiotic Compositions for Treatment of the Eye, Ear and Nose</i> (Alcon)	AL002-001002-001023		None
PTX-0028	9/22/2000	USPN 09/646,797, Cagle et al., <i>Antibiotic Compositions for Treatment of the Eye, Ear and Nose</i> , WO 00/18386 (Alcon)	AL002-000127-000153		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0029	8/2001	Project Initiation Form for Avelox Tablets	T009596	PDX 029	Highly Confidential (object to use in open Court)
PTX-0030	10/4/2006	Organizational Chart (Marketing)	T001286	PDX 030	Highly Confidential (object to use in open Court)
PTX-0031	6/12/2006	Sales Forecasts for 2009 Launches (Includes Moxifloxacin Ophthalmic)	T001569-001570	PDX 031	Highly Confidential (object to use in open Court)
PTX-0033	9/29/2006	2005 Strategic Plan (Includes Moxifloxacin Ophthalmic)	T002516-002541	PDX 033	Highly Confidential (object to use in open Court)
PTX-0034	11/12/2003	Forecasted Bottles for Israel Capacity Planning (Moxifloxacin Ophthalmic Solution) 7/2013 – 6/2016	T001502-001503	PDX 034	Highly Confidential (object to use in open Court)
PTX-0035	11/12/2003	Forecasted EU's (ML's) for Israel Capacity Planning (Moxifloxacin Ophthalmic Solution) 7/2013 – 6/2016	T001504-001505	PDX 035	Highly Confidential (object to use in open Court)
PTX-0036	11/12/2003	Forecasted Dollars for Israel Capacity Planning (Moxifloxacin Ophthalmic Solution) 7/2013 – 6/2016	T001506-001507	PDX 036	Highly Confidential (object to use in open Court)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0037	12/21/2005	Pipeline Management Information for Moxifloxacin Ophthalmic Solution	T001520	PDX 037	Highly Confidential (object to use in open Court)
PTX-0038	4/16/2003	PIT Minutes for 4/16/2003 (Included in Email)	T001560-001567	PDX 038	Highly Confidential (object to use in open Court)
PTX-0042		Teva Ophthalmic Sales and Requirements 2006 – 2008	T001501	PDX 042	Highly Confidential (object to use in open Court)
PTX-0043		IMS Sales Data for Ciloxan, Vigamox and Tobrex 11/2001 – 9/2003	T001486-001494	PDX 043	Highly Confidential (object to use in open Court)
PTX-0050	3/13/2005	Teva Project Review Status Report for Moxifloxacin Ophthalmic Solution	T005179-005182	PDX 050	Highly Confidential (object to use in open Court)
PTX-0054	3/2006	Report of Sales and % Change as of 12/2005 for Moxifloxacin HCl Tablets and Moxifloxacin Ophthalmic Solution	T001324-001331	PDX 054	Highly Confidential (object to use in open Court)
PTX-0055		TEVA ISRAEL PROJECTS, SALES BY STRENGTH as of 12/2004 for Moxifloxacin HCl Tablets and Moxifloxacin Ophthalmic Solution	T001345-001361	PDX 055	Highly Confidential (object to use in open Court)
PTX-0056	12/21/2005	ANDA 78-073 for Moxifloxacin HCl Ophthalmic Solution: Submission Cover Letter and TOC	T000001-000007	PDX 056	Highly Confidential (object to use in open Court)



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0057	12/10/2004	ANDA 77-473 Moxifloxacin HCl Tablets: Submission Cover Letter, TOC and Analytical Method Validation Reports: Assay and Related Substances Determination and RR-Isomer Content by Chiral HPLC	T400001-000087	PDX 057	Highly Confidential (object to use in open Court)
PTX-0058	12/10/2004	ANDA 77-473 Moxifloxacin HCl Tablets: Information Required Under 21 CFR Comparison of Generic Drug v. Reference Listed Drug and Labeling Information	T404329-000371	PDX 058	Highly Confidential (object to use in open Court)
PTX-0059	2/21/2006	Teva Notice Letter for Moxifloxacin HCl Ophthalmic Solution	T001204-001223	PDX 059	None
PTX-0060	3/7/2007	Teva Notice Letter for Moxifloxacin HCl Tablets	T404959-404980	PDX 060	None
PTX-0061	12/10/2004	Patent Certification for Moxifloxacin HCl Tablets	T404421-404422	PDX 061	Highly Confidential (object to use in open Court)
PTX-0062	3/7/2007	Amendment – Revised Certification for Moxifloxacin HCl Tablets	T404788	PDX 062	Highly Confidential (object to use in open Court)
PTX-0063	11/30/2006	FDA Approval Letter for Moxifloxacin HCl Tablets	T404982-404984	PDX 063	None
PTX-0065		Excerpt from Teva's ANDA 78-073: Section XV.3: Analytical Methods- Method Validation	T000780-000781; T000822-000843	PDX 065	Highly Confidential (object to use in open Court)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0066	10/10/2003	DRL Analytical Methods and Specification for Moxifloxacin HCl and Related Substances by HPLC and RR Isomer Content by HPLC	DRLMOX-0000457-0000460	PDX 066	FRE 401/402/403 (irrelevant)
PTX-0067	9/25/2005	Analytical Work Materials for R,R-Isomer Content of Moxifloxacin HCl Ophthalmic Solution (Batch K-35730)	T003690-003712	PDX 067	Highly Confidential (object to use in open Court)
PTX-0068		ANDA 77-473 Moxifloxacin HCl Tablets Analysis of Active Ingredient: DMF; Certificates of Analysis; Reference Standard Characterization; Analytical Method Summaries	T400795-400898	PDX 068	Highly Confidential (object to use in open Court)
PTX-0069	9/19/2007	Responsive Expert Report of Dr. Daniel W. Armstrong			Highly Confidential (object to use in open Court)  FRE 801/802 (hearsay)  FRE 401/402/403 (irrelevant to the extent issues no longer in the case are addressed)
PTX-0070		Curriculum Vitae of Dr. Daniel W. Armstrong	Armstrong A		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0071	1987	Florance et al., <i>High-Performance Liquid Chromatographic Separation of Peptide and Amine Acid Stereoisomers</i> , J. Chromatography, 414:313-22 (1987)	Armstrong BB		None
PTX-0072	1986	Manabe, <i>Optical Configuration of Alanine Detected in the Lead Blades of Japonica Rice Plants Fed with D-Alanine</i> , Soil Sci. Plant Nutr., 32:327-31 (1986)	Armstrong CC		None
PTX-0073		Excerpt from Dr. Reddy's Laboratories' ANDA No. 76-938: Section 8.3: Method validation protocol and report: Chiral purity by HPLC method for moxifloxacin hydrochloride	DRLMOX000578-000608		FRE 401/402/403 (irrelevant)
PTX-0074		Excerpt from Teva's ANDA No. 77-437: Moxifloxacin HCl - RR-Isomer Content- Method Validation	T400066-000087		Highly Confidential (object to use in open Court)
PTX-0075	9/25/2006	Defendant Teva Pharmaceuticals USA, Inc.'s Responses to Plaintiffs' First Set of Interrogatories, Nos. 1-5.			None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0076	4/16/2007	Defendant Teva Pharmaceuticals USA, Inc.'s Responses to Plaintiffs' Second Set of Interrogatories, Nos. 6-19.			None
PTX-0077	6/26/2007	Teva's Responses to Plaintiffs' Third Set of Interrogatories, Nos. 20-24			None
PTX-0078	6/26/2007	Teva's Response to Plaintiffs' Fourth Set of Interrogatories, No. 25			None
PTX-0079	9/4/2007	Teva's Response to Plaintiffs' Fifth Set of Interrogatories, No. 26			None
PTX-0080	10/4/2007	Teva Supplemental Response to Plaintiff's Fifth Set of Interrogatories, No. 26			None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0081	11/27/2007	Defendant's Supplemental Responses to Plaintiffs' Interrogatories, Nos. 3, 7-9, 16, 18, 23, and 24			None
PTX-0082	8/3/2007	First Amended Answer and Affirmative Defenses of Defendant Teva Pharmaceuticals USA, Inc. Civil Action No. 06-234-SLR			None
PTX-0083	8/3/2007	First Amended Answer and Affirmative Defenses of Defendant Teva Pharmaceuticals USA, Inc. Civil Action No. 07-195-SLR			None
PTX-0084		Petersen et al., <i>BAY Y3118, a Novel 4- Quinolone: Synthesis and In Vitro Activity</i> , (Poster)	BL009-036178		None
PTX-0085		Sample of Moxifloxacin with Certificates of Analysis (with translation)	AL022-000001-010; BL027- 000001-004		FRE 401/402/403 (irrelevant)
PTX-0086	12/14/2007	Excerpt of Kathleen Alford's Lab Notebook	AL022-000011-014		FRE 401/402/403 (irrelevant) FRE 701 (improper lay testimony)
PTX-0087	1995	Hecht, <i>Ophthalmic Preparations</i> , Remington: The Science and Practice of Pharmacy (Gennaro ed.), 19th ed., Vol. II, Chapter 89:1563-1576 (1995)	AL023-000001-022		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0088	7/6/1993	Bayer Data (with translation)	BL002-028585-588		FRE 401/402/403 (irrelevant) FRE 106 (incomplete document) FRE 901/902 (authenticity as to data)
PTX-0089	1/4/1999	Alcon Research Compound Submission	AL007-023353		FRE 106 (incomplete document)
PTX-0089A	1/4/1999	Alcon Research Compound Submission	AL007-023353-023359		
PTX-0101		Curriculum Vitae of Loyd V. Allen, Ph.D		PDX 101	None
PTX-0102		Consulting Agreement of Loyd V. Allen, Ph.D		PDX 102	None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0114	1996	Petersen <i>et al.</i> , <i>Synthesis and in vitro Activity of BAY 12-8039, A New 8-Methoxyquinolone</i> , ICAAC (1996) (Poster with enlargements)		PDX 114	None
PTX-0115	1996	Petersen <i>et al.</i> , <i>Synthesis and in vitro Activity of BAY 12-8039, A New 8-Methoxy-quinolone</i> , 36th ICAAC (1996) (Abstract)	BL014-011453-011455	PDX 115	None
PTX-0125	7/20/1995	Second Bremm Declaration	BT002-001726-001735	PDX 125	None
PTX-0126	12/2/1994	First Bremm Declaration	BT002-001721-001725	PDX 126	None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0130	7/27/2007	Expert Report of Dr. Edward C. Taylor		DDX 127	Highly Confidential (object to use in open Court)  FRE 801/802 (hearsay)  FRE 401/402/403 (irrelevant to the extent issues no longer in the case are addressed)
PTX-0131		Curriculum Vitae of Dr. Edward C. Taylor		DDX 129	Highly Confidential (object to use in open Court)  FRE 801/802 (hearsay)  FRE 401/402/403 (irrelevant to the extent issues no longer in the case are addressed)
PTX-0132	1986	Domagala et al., 1-Ethyl-7-[3]([ethylamino)methyl]-1-pyrrolidinyl]-6,8-difluoro-1,4-dihydro-4-oxo-3-quinoline-carboxylic Acid. New Quinolone Antibacterial with Potent Gram-Positive Activity. J. Med. Chem. 29: 445-48 (1986)	Taylor E		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0133	12/1985	Cohen et al., <i>In Vitro Activity of Cf-934, a Quinolone Carboxylic Acid Active against Gram-Positive and -Negative Bacteria</i> , Antimicrobial Agents and Chemotherapy, 28(6):766-72 (1985)	Taylor F		None
PTX-0134	1977	Albrecht, <i>Development of Antibacterial Agents of Nalidixic Acid Type</i> , Progress in Drug Res., vol. 21, (Jucker ed.), Birkhauser, 9-104 (1977)	BL005-030407-030458		None
PTX-0135	1997	Klugman and Capper, <i>Concentration-dependent Killing of Antibiotic-resistant Pneumococci by the Methoxyquinolone Moxifloxacin</i> , J. Antimicrobial Chemotherapy, 40:797-02 (1997)	Taylor H		None
PTX-0136	7/1998	Østergaard et al., <i>Evaluation of Moxifloxacin, a New 8-Methoxyquinolone, for Treatment of Meningitis Caused by a Penicillin-Resistant Pneumococcus in Rabbits</i> , Antimicrobial Agents and Chemotherapy, 42:1706-12 (1998)	Taylor I		None
PTX-0137	1997	Woodcock et al., <i>In Vitro Activity of Bay 12-8039, A New Fluoroquinolone, Antimicrobial Agents and Chemotherapy</i> , 41(1):101-06 (1997)	Taylor J		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0138	3/13/98	WHO Drug Information, Vol. 11, No. 4, 279 (1997) (INN Proposal for moxifloxacin)	Taylor K		None
PTX-0139	7/28/98	WHO Drug Information, Vol. 12, No. 2, 187 (1998) (INN Recommendation of moxifloxacin)	Taylor L		None
PTX-0140	2005	Van Bambeke <i>et al.</i> , <i>Quinolones in 2005: an Update</i> , Clin. Micro. Infect. 11: 256-80 (2005)	Taylor Q		None
PTX-0141	7/1984	Loudon, <i>Organic Chemistry</i> , Ch. 7 at 212 and Ch. 8 at 266-67 (1984)		DDX 131	None
PTX-0142	1983	The Merck Index. An Encyclopedia of Chemicals, Drugs, and Biologicals, at 258, 356, and 520-22 (10th ed. 1983)	Taylor S		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0143	1971	Allinger and Eliel (Editors), <i>Topics In Stereochemistry</i> , 6:138-39 (1971)	Taylor T		None
PTX-0144	3/11/2004	Notice of Final Determination re Patent Term Extension for U.S. Patent No. 4,990,517	BT002-001424-425		FRCP 34 / FRE 403 (not produced)
PTX-0145	12/15/1989	Moran et al., <i>The 6S- and 6R-Diastereomers of 5,10-Dideaza-5,6,7,8-tetrahydrofolate Are Equiaxial Inhibitors of de Novo Purine Synthesis</i> , J. Bio. Chem., 264(35): 21047-51 (1989)	Taylor V		None
PTX-0146	1982	Solladié et al., <i>Asymmetric Synthesis of Five- and Six-Membered Lactones from Chiral Sulfoxides: Application to the Asymmetric Synthesis of Insect Pheromones, (R)-(+)-δ-n-Hexadecanolactone Synthesis of Insect Pheromones, (R)-(+)-γ-n-Dodecanolactone</i> , J. Org. Chem., 47:91-94 (1982)	Taylor X		None
PTX-0147	1986	Denis et al., <i>An Efficient, Enantioselective Synthesis of Taxol Side Chains</i> , J. Org. Chem., 51(1):46-50 (1986)	Taylor Y		None
PTX-0148	7/14/2007	Solorio and Jennings, <i>Total Synthesis and Absolute Configuration Determination of (+)-Bruguierol C</i> , J. Org. Chem. Note (published on web July 14, 2007)	Taylor Z		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0149	1978	Newman, <i>Optical Resolution Procedures for Chemical Compounds</i> , Vol. 1: <i>Amines and Related Compounds</i> , at 35, 38-39, 117-18, 199-200, 221-22, 424 and 429-30 (1978)	Taylor AA		None
PTX-0150	11/2003 and 12/10/2003	Excerpts from Dr. Reddy's moxifloxacin hydrochloride tablet ANDA and Dr. Reddy's Drug Master File for moxifloxacin hydrochloride	DRLMOX000001-000011, DRLMOX000477-000480, DRLMOX0005020, DRLMOX0005049-0005058		None
PTX-0151	6/13/05	Stipulation of infringement by Dr. Reddy in <i>Bayer v. Dr. Reddy</i> , Case No. 04-179-SLR (D. Del.)	Taylor II		None
PTX-0152	1997	WHO Guidelines on the use of International Nonproprietary Names (INNs) for Pharmaceutical Substances (1997)	Taylor JJ		None
PTX-0153	9/19/2007	Responsive Expert Report of Dr. Edward C. Taylor		DDX 128	Highly Confidential (object to use in open Court)  FRE 801/802 (hearsay)  FRE 401/402/403 (irrelevant to the extent issues no longer in the case are addressed)
PTX-0154	5/1988	Excerpt from <i>Abstracts of the Annual Meeting of the American Society for Microbiology 1988</i> , abstracts A-13 through A-17 re: PD 117,596 and	BT002-006486-006491		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		PD 127,391			
PTX-0155	1994	Domagala, <i>Structure-Activity and Structure-Side-Effect Relationships for the Quinolone Antibacterials</i> , 33 J. Anti. Chem. 33:685-06 (1994)	Taylor Responsive 3		None
PTX-0156	1988	Sanchez et al., <i>Quinolone Antibacterial Agents, Synthesis and Structure-Activity Relationships of 8-Substituted Quinolone-3-Carboxylic Acids and 1,8-Naphthyridine-3-Carboxylic Acids</i> , J. Med. Chem., 31:983-91 (1988)	BT002-006095-006103		None
PTX-0157	4/25/1984	EP Application 0106489 A2, Culbertson et al., <i>Antibacterial Agents</i> (Warner Lambert)	DRLMOX 027092-027216	DDX 81	None
PTX-0158		Data Comparison: 8-Hydrogen and 8-Methoxy: Culbertson '489	BT002-013533-013534		FRE 801/802 (hearsay) FRE 106 (incomplete document) FRE 401/402/403 (irrelevant)
PTX-0159	1985	Wentland and Cornett, <i>Quinolone Antibacterial Agents</i> , Ann. Rpts. Med. Chem., 20(Ch. 15):145-54 (1985)	Taylor Responsive 8		None
PTX-0160	1986	Cornett and Wentland, <i>Quinolone Antibacterial Agents</i> , Ann. Rpts. Med. Chem., 21(Ch. 14):139-48 (1986)	Taylor Responsive 9		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0161	1987	Fernandes and Chu, <i>Quinolones</i> , Ann. Rpts. Med. Chem., 22 (Ch. 12):117-26 (1987)	BT002-009208-009219		None
PTX-0162	1988	Fernandes and Chu, <i>Quinolone Antibacterial Agents</i> , Ann. Rpts. Med. Chem., 23 (Ch. 14):133-40 (1988)	BT002-009192-009207		None
PTX-0163	11/17/2005	Certified Copy of EP Application 0195316 A1, <i>Irikura et al., Quinolonecarboxylic Acid Derivatives (Kyorn)</i>	RT001-012950-012993		None
PTX-0164	1988	Evans et al., <i>Methods for drug discovery: Development of potent, selective, orally effective cholecystokinin antagonists</i> , J. Med. Chem., 31(12): 2235-46 (1988)	Taylor Responsive 15		None
PTX-0165	12/17/1992	Maliski et al., <i>The Whole Molecule Design Approach to Drug Discovery</i> , Drug Design and Discovery, 9:1-9 (1992)	Taylor Responsive 16		None
PTX-0166	1988	Domagala et al., <i>7-Substituted 5-Amino-1-cyclopropyl-6,8-difluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic Acids: Synthesis and Biological Activity of a New Class of Quinolone Antibacterials</i> , J. Med. Chem. 31(3):503-06 (1988)	Taylor Responsive 17		None
PTX-0167		USSN 08/026,906 Application	BL001-014002-014135		None
PTX-0170	9/19/2007	Responsive Expert Report of Dr. George G.			FRE 801/802 (hearsay)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		Zhanel			
PTX-0171		Curriculum Vitae of Dr. George G. Zhanel		DDX 121	None
PTX-0172	1991	Steinert, <i>Current Therapy for Bacterial Keratitis and Bacterial Conjunctivitis</i> , Am. J. of Ophthalmol. 112:10S-14S (1991)	Zhanel 7		None
PTX-0173	2001	Zhanel et al., <i>In Vitro Pharmacodynamic Modeling Simulating Free Serum Concentrations of Fluoroquinolones Against Multidrug-resistant Streptococcus pneumoniae</i> , J. Anti. Chem., 47:435-40 (2001)	BT002-009453-009458		None
PTX-0174	2001	Zhanel, <i>Influence of Pharmacokinetic and Pharmacodynamic Principles on Antibiotic Selection</i> , Cur. Infect. Dis. Rpts., 3:29-34 (2001)	BT002-009465-009470		None
PTX-0175	6/1996	Bower et al., <i>Fluoroquinolones in the Treatment of Bacterial Keratitis</i> , Am. J. Ophthalmol. 121(6):712-15 (1996)	Zhanel 10		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0176	6/1998	Masket, <i>Preventing, diagnosing and treating endophthalmitis</i> , J. Cataract Refract. Surg. 24:725-26 (1998)	Zhanet 11		None
PTX-0177	6/2001	Doern et al., <i>Antimicrobial Resistance Among Clinical Isolates of Streptococcus pneumoniae in the United States During 1999-2000, Including a Comparison of Resistance Rates Since 1994-1995</i> , Anti. Agents Chem., 45:1721-29 (2001)	BT002-009167-009175		None
PTX-0178	7/22/1999	Chen et al., <i>Decreased Susceptibility of Streptococcus pneumoniae to Fluoroquinolones in Canada</i> , N. Engl. J. Med., 341:233-39 (1999)	BT002-009134-009140		None
PTX-0179	3/7/2002	Davidson et al., <i>Resistance to Levofloxacin and Failure of Treatment of Pneumococcal Pneumonia</i> , N. Engl. J. Med., 346:747-50 (2002)	BT002-009163-009166		None
PTX-0180	9/2003	Elfrig et al., <i>Endophthalmitis Caused by Pseudomonas aeruginosa</i> , Ophthalmology 110(9):1714-17 (2003)	Zhanet 15		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0181	5/1986	Alfonso, <i>Ulcerative keratitis associated with contact lens wear</i> . Am. J. Ophthalmol. 101(4):429-33 (1986)	Zhanel 16		None
PTX-0182	7/1999	Goldstein et al., <i>Emerging Fluoroquinolone Resistance in Bacterial Keratitis: A 5 year review</i> , Ophthalmology, 106(7):1313-18 (1999)	Zhanel 17		None
PTX-0183	3/15/1998	Goldstein et al., <i>Emerging Fluoroquinolone Resistance in Bacterial Keratitis: A 5 year review</i> , IOVS 39(4): 4951-B702 (1998)	Zhanel 18		None
PTX-0184	9/1998	Chaudhry et al., <i>Scleral Buckle Infection with Ciprofloxacin-Resistant Pseudomonas aeruginosa</i> , Arch. Ophthalmol., 116:1251 (1998)	Zhanel 19		None
PTX-0185	1996	Knauf et al., <i>Susceptibility of Corneal and Conjunctival Pathogens to Ciprofloxacin</i> , Cornea, 15(1):66-71 (1996)	Zhanel 21		None
PTX-0186	3/15/1995	Hodge et al., <i>Frequency of Recovery of Ciprofloxacin-Resistant Ocular Isolates Following Topical Ciprofloxacin Therapy</i> , Invest. Ophthalmol. and Vis. Science, 36(4):754-662 (1995) (Abstract)	Zhanel 22		None
PTX-0187	4/1993	Maffett and Day, <i>Ciprofloxacin-resistant Bacterial Keratitis</i> , Am. J. Ophthalmol., 115(4):545-46 (letter to Ed.) (1993)	Zhanel 23		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0188	8/2000	Alexandrakis et al., <i>Shifting Trends in Bacterial Keratitis in South Florida and Emerging Resistance to Fluoroquinolones</i> , Ophthalmology, 107(8):1497-1502 (2000)	Zhanel 24		None
PTX-0189	10/1999	Chaudhry et al., <i>Emerging Ciprofloxacin-Resistant Pseudomonas aeruginosa</i> , Am. J. Ophthalmology, 128(4):509-10 (1999)	Zhanel 25		None
PTX-0190	1/1999	Kunimoto et al., <i>In Vitro Susceptibility of Bacterial Keratitis Pathogens to Ciprofloxacin</i> , Emerging Resistance, Ophthalmology, 106(1):80-85 (1999)	Zhanel 26		None
PTX-0191	7/1999	Garg et al., <i>Ciprofloxacin-resistant Pseudomonas Keratitis</i> , Ophthalmology, 106(7):1319-23 (1999)	Zhanel 27		None
PTX-0192	3/2004	Hwang, <i>Fluoroquinolone Resistance in Ophthalmology and the Potential Role of Newer Ophthalmic Fluoroquinolones</i> , Survey Ophthalmology 49(2):S79 (2004)	Zhanel 28		None
PTX-0193	3/2004	Blondeau, <i>Fluoroquinolones: Mechanism of Action, Classification, and Development of Resistance</i> , Survey Ophthalmology, 49(2):S73-78 (2004)	Zhanel 29		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0194	1998	Bail <i>et al.</i> , <i>Therapeutic Advances of New Fluoroquinolones</i> , Expert Opinion on Investigational Drugs, 7(5):761-83 (1998)	Zhanel 30		None
PTX-0195		Orange Book listing for Ciloxan	Zhanel 31		None
PTX-0196		Orange Book listing for Ocuflox	Zhanel 32		None
PTX-0197	1991	Paton and Reeves, <i>Clinical Features and Management of Adverse Effects of Quinolone Antibacterials</i> , Drug Safety, 6(1):8-27 (1991)	Zhanel 34		None
PTX-0198	2/1983	Swanson <i>et al.</i> , <i>Norfloxacin Disposition After Sequentially Increasing Oral Doses</i> , Anti. Agents	Zhanel 35		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		Chem., 23:284-288 (1983)			
PTX-0199	10/1989	Smith et al., <i>Evaluation of Difloxacin in the Treatment of Uncomplicated Urethral Gonorrhea in Men</i> , Anti. Agents Chem., 33:1721-23 (1989)	Zhanel 36		None
PTX-0200	1990	Christ, <i>Central Nervous System Toxicity of Quinolones: Human and Animal Findings</i> , J. Anti. Chem., 26(Suppl. B):219-25 (1990)	Zhanel 37		None
PTX-0201	1990	Defoin et al., <i>Syndrome Psychiatrique Aigu et Quinolones</i> , J. Toxicol. Clin. Exp. 10:469-72 (1990)	Zhanel 38		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiffs' translation, or offer a more accurate translation, if necessary..
PTX-0202	1993	Norby and Lietman, <i>Safety and Tolerability of Fluoroquinolones</i> , Drugs, 45(Suppl. 3):59-64 (1993)	Zhanel 39		None
PTX-0203	7/1998	Kimura et al., <i>Drug-Induced Pneumonitis with Eosinophilic Infiltration Due to Tosufloxacin Tosilate</i> , Nihon Kokyuki Gakkai Zasshi, 36(7):618-22 (1998) (Abstract)	Zhanel 40		None
PTX-0204	1/1988	Fernandes et al., <i>A-61827 (A-60969), a New Fluoronaphthyridine with Activity Against Both Aerobic and Anaerobic Bacteria</i> , Anti. Agents Chem. 32(1):27-32 (1988)	Zhanel 41		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0205	4/1989	Suzuki and Nagata, <i>Clinical Efficacy of T-3262, a New Quinolone Compound, on Urinary Tract Infection in 1988</i> , Hinyokika Kiyo, 35(4):717-26 (1989) (Abstract)	Zhanel 42		None
PTX-0206	7/1989	Aoki et al., <i>Clinical Trial of T-3262 (Tosufloxacin Tosilate) on Salmonella enteritis, and Fecal Concentration and Change in the Fecal Microflora in the Acute Diarrheal Patients</i> , Kansenshogaku Zasshi, 63(7):659-75 (1989) (Abstract)	Zhanel 43		None
PTX-0207	3/1994	Sakurai et al., <i>Study on Clinical Effects of Tosufloxacin (TFLX) and the Long-Term Low Dose Therapy for Prophylaxis of Recurrent Urinary Tract Infection</i> , Hinyokika Kiyo, 40(3):279-84 (1994) (Abstract)	Zhanel 44		None
PTX-0208	4/1992	Fukushima et al., <i>Clinical Studies on Tosufloxacin (TFLX) in Urology</i> , Hinyokika Kiyo, 38(4):501-06 (1992) (Abstract)	Zhanel 45		FRE 403 (not provided with expert report)
PTX-0209	1998	Leophonte et al., <i>Trovafloxacin Versus Amoxicillin/Clavulanic Acid in the Treatment of Acute Exacerbations of Chronic Obstructive Bronchitis</i> , Eur. J. Clin. Microbiol. Infect. Dis., 17:434-40 (1998)	Zhanel 45A		None
PTX-0210	1998	O'Doherty et al., <i>Treatment of Acute Exacerbations of Chronic Bronchitis: Comparison</i>	Zhanel 46		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		<i>of Trovafloxacin and Amoxicillin in a Multicentre, Double-Blind, Double-Dummy Study</i> , Eur. J. Clin. Microbiol. Infect. Dis., 17:441-46 (1998)			
PTX-0211	1998	Tremolieres et al., <i>Trovafloxacin Versus High-Dose Amoxicillin (1 g Three Times Daily) in the Treatment of Community-Acquired Bacterial Pneumonia</i> , Eur. J. Clin. Microbiol. Infect. Dis., 17:447-53 (1998)	Zhanel 47		None
PTX-0212	1998	Williams and Hopkins, <i>Safety of Trovafloxacin in Treatment of Lower Respiratory Tract Infections</i> , Eur. J. Clin. Microbiol. Infect. Dis., 17:454-58 (1998)	Zhanel 48		None
PTX-0213	1/1998	Jones et al., <i>Randomized Trial of Trovafloxacin and Ofloxacin for Single-Dose Therapy of Gonorrhea</i> , Am. J. Med., 104:28-32 (1998)	Zhanel 49		None
PTX-0214	6/9/1999	FDA Issues Public Health Advisory on Liver Toxicity Associated with the Antibiotic Trovan	Zhanel 50		None
PTX-0215	1/1998	Chodosh et al., <i>Efficacy and Safety of a 10-Day Course of 400 or 600 Milligrams of Grepafloxacin Once Daily for Treatment of Acute Bacterial Exacerbations of Chronic Bronchitis: Comparison with a 10-Day Course of 500 Milligrams of Ciprofloxacin Twice a Day</i> , Anti. Agents Chem., 42(1):114-20 (1998)	Zhanel 51		None
PTX-0216	8/1997	Hook et al., <i>Comparison of Single-Dose Oral Grepafloxacin with Cefixime for Treatment of Uncomplicated Gonorrhea in Men</i> , Anti. Agents	Zhanel 52		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		Chem., 41(8):1843-45 (1997)			
PTX-0217	2/1998	Wise et al., <i>Pharmacokinetics and Inflammatory Fluid Penetration of Clinafloxacin</i> , <i>Anti. Agents Chem.</i> , 42(2):428-30 (1998)	Zhanel 54		None
PTX-0218	1/1997	Cormican and Jones, <i>Antimicrobial Activity and Spectrum of LB20304, a Novel Fluoronaphthyridone</i> , <i>Anti. Agents Chem.</i> , 41(1):204-11 (1997)	Zhanel 55		None
PTX-0219	9/27/2004	<i>Gemifloxacin (Factive)</i> , <i>The Medical Letter</i> , 46(1192):78-79 (2004)	BT002-009252-009254		None
PTX-0220	12/1995	Nakashima et al., <i>Single- and Multiple-Dose Pharmacokinetics of AM-1155, a new 6-Fluoro-8-Methoxy Quinolone, in Humans</i> , <i>Anti. Agents Chem.</i> , 39(12):2635-40 (1995) (Abstract)	Zhanel 57		None
PTX-0221	7/2003	Canadian Adverse Reaction Newsletter July 2003;13(3)	Zhanel 58		None
PTX-0222	1986	Ashley, <i>The Anti-Bacterial Activity of Topical Anti-Infective Eye Preparations</i> , <i>Med. Lab. Sci.</i> , 43:157-62 (1986)	Zhanel 60		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0223	8/1998	Stass et al., Pharmacokinetics, Safety, and Tolerability of Ascending Single Doses of Moxifloxacin, a New 8-Methoxy Quinolone, Administered to Healthy Subjects, Anti. Agents Chem., 42(8):2060-65 (1998)	Zhanel 61		None
PTX-0224	7/1998	Schmuck et al., Determination of the Excitatory Potencies of Fluoroquinolones in the Central Nervous System by an In Vitro Model, Anti. Agents Chem., 42(7):1831-36 (1998)	Zhanel 62		None
PTX-0225	8/1997	Fass, In Vitro Activity of Bay 12-8039, a New 8-Methoxyquinolone, Anti. Agents Chem., 41(8):1818-24 (1997)	Zhanel 63		None
PTX-0226	1997	Bauernfeind, Comparison of the Antibacterial Activities of the Quinolones Bay 12-8039, Gatifloxacin (AM 1155), Trovafloxacin, Clinafloxacin, Levofloxacin and Ciprofloxacin, J. Anti. Chem., 40:639-51 (1997)	Zhanel 65		None
PTX-0227	8/1991	Javitt et al., National Outcomes of Cataract Extraction, Endophthalmitis Following Inpatient Surgery, Arch. Ophthalmol., 109:1085-89 (1991)	Zhanel 68		None
PTX-0228	10/2005	Donnenfeld, ASCRS White Paper: Management of Infectious Keratitis Following Laser In Situ Keratomileusis, J. Cataract Refract. Surg., 31:2008-11 (2005)	Zhanel 69		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0229	10/2003	Solomon et al., <i>Special Report, Infectious Keratitis After Laser In Situ Keratomileusis: Results of an ASCRS Survey</i> , J. Cataract Refract. Surg., 29:2001-06 (2003)	Zhanel 70		None
PTX-0230	2/1991	Kattan et al., <i>Nosocomial Endophthalmitis Survey: Current Incidence of Infection After Intraocular Surgery</i> , Ophthalmology, 98(2):227-38 (1991)	Zhanel 71		None
PTX-0231	6/1998	Aaberg et al., <i>Nosocomial Acute-Onset Postoperative Endophthalmitis Survey</i> , Ophthalmology, 105(6):1004-10 (1998)	Zhanel 72		None
PTX-0232	1982	Fraunfelder et al., <i>Fatal Aplastic Anemia Following Topical Administration of Ophthalmic Chloramphenicol</i> , Am. J. Ophthalmol., 93(3):356-60 (1982)	Zhanel 73		None
PTX-0233	1987	Fraunfelder and Meyer, <i>Systemic Reactions to Ophthalmic Drug Preparations</i> , Medical Toxicology, 2:287-93 (1987)	Zhanel 74		None
PTX-0234	1995	Diamond et al., <i>Topical 0.3% Ciprofloxacin, Norfloxacin, and Ofloxacin in Treatment of Bacterial Keratitis: a New Method for Comparative Evaluation of Ocular Drug Penetration</i> , British J. Ophthalmol., 79:606-09 (1995)	Zhanel 75		None
PTX-0235	4/1987	Jones and Barry, <i>Antimicrobial Activity and Spectrum of LY146032, a Lipopeptide Antibiotic, Including Susceptibility Testing</i>	Zhanel 77		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		<i>Recommendations, Anti. Agents Chem.</i> , 31(4):625-29 (1987)			
PTX-0236	2000	<i>Pestova et al., Intracellular Targets of Moxifloxacin: a Comparison with Other Fluoroquinolones</i> , J. Antimicrob. Chem., 45:583-90 (2000)	Zhanel 78		None
PTX-0237	1/2007	<i>Ong-Tone, Aqueous Humor Penetration of Gatifloxacin and Moxifloxacin Eyedrops Given by Different Methods Before Cataract Surgery</i> , J. Cataract Refract. Surg., 33:59-62 (2007)	Zhanel 79		None
PTX-0238	1/5/2005	<i>Kim et al., Ocular Penetration of Moxifloxacin 0.5% and Gatifloxacin 0.3% Ophthalmic Solutions Into the Aqueous Humor Following Topical Administration Prior to Routine Cataract Surgery</i> , Current Medical Research and Opinion, 21(1):93-94 (2005)	Zhanel 80		None
PTX-0239	11/2005	<i>Kim et al., Aqueous Penetration and Biological Activity of Moxifloxacin 0.5% Ophthalmic Solution and Gatifloxacin 0.3% Solution in Cataract Surgery Patients</i> , Ophthalmology, 112(11):1992-96 (2005)	Zhanel 81		None
PTX-0240	3/2005	<i>Solomon et al., Penetration of Topically Applied Gatifloxacin 0.3%, Moxifloxacin 0.5%, and Ciprofloxacin 0.3% in Aqueous Humor</i> , Ophthalmology, 112(3):466-69 (2005)	Zhanel 82		None
PTX-0241	2004	<i>Robertson et al., Absorption and Distribution of Moxifloxacin, Ofloxacin and Gatifloxacin into</i>	Zhanel 83	DDX 115	None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		<i>Ocular Tissues and Plasma Following Topical Ocular Administration to Pigmented Rabbits, Invest. Ophthalmology and Vis. Science, 45:4906-B230 (2004) (ARVO E-Abstract)</i>			
PTX-0242	2004	Thibodeaux et al., <i>Quantitative Comparison of Fluoroquinolone Therapies of Experimental Gram-Negative Bacterial Keratitis</i> , Current Eye Research, 28(5):337-42 (2004)	Zhanel 85		None
PTX-0243	3/2005	Aliprandis et al., <i>Comparative Efficacy of Topical Moxifloxacin Versus Ciprofloxacin and Vancomycin in the Treatment of P. aeruginosa and Ciprofloxacin-Resistant MRSA Keratitis in Rabbits</i> , Cornea 24(2):201-05 (2005)	Zhanel 87		None
PTX-0244	4/2004	Leaming, Practice Styles and Preferences of ASCRS Members—2003 Survey, J. Cataract Refract. Surg., 30:892-900 (2004)	Zhanel 88		None
PTX-0245	11/2005	Schlech and Alfonso, <i>Overview of the Potency of Moxifloxacin Ophthalmic Solution 0.5% (VIGAMOX®)</i> , Survey Ophthalmology, 50(Suppl. 1):S7-A15 (2005)	Zhanel 89		None
PTX-0246	11/1986	Wright, <i>Cefsulodin</i> , Drug Intel. and Clin. Pharm., 20:845-49 (1986)	BT002-009435-009439		None
PTX-0247	7/6/2005	Stipulation and Order- Unexpected Properties from <i>Bayer v. Dr. Reddy</i> , Case No. 04-179-SLR (D. Del.)	Zhanel 106		FRE 401/402/403 (irrelevant)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0248	1999	Soman et al., Concentrations of Moxifloxacin in Serum and Pulmonary Compartments Following a Single 400 mg Oral Dose in Patients Undergoing Fibre-Optic Bronchoscopy, J. Anti. Chem., 44(6):835-38 (1999)	BT002-009386-009389		None
PTX-0249	2001	Nagai et al., Single- and Multi-Step Resistance Selection Study of Gemifloxacin Compared with Trovafloxacin, Ciprofloxacin, Gatifloxacin and Moxifloxacin in Streptococcus pneumoniae, J. Anti. Chem., 48(3):365-74 (2001)	BT002-009329-009338		None
PTX-0250	8/2003	Allen et al., Activities of Mutant Prevention Concentration-Targeted Moxifloxacin and Levofloxacin against Streptococcus pneumoniae in an in vitro Pharmacodynamic Model, Anti. Agents Chem., 47(8):2606-14 (2003)	BT002-009067-009075		None
PTX-0251	2/2001	Blondeau et al., Mutant Prevention Concentrations of Fluoroquinolones for Clinical Isolates of Streptococcus pneumoniae, Anti. Agents Chem., 45(2):433-38 (2001)	BT002-009109-009114		None
PTX-0252	2002	Boswell et al., Comparison of the In Vitro Activities of Several New Fluoroquinolones Against Respiratory Pathogens and Their Abilities to Select Fluoroquinolone Resistance, J. Anti. Chem., 50:495-502 (2002)	BT002-009120-009127		None
PTX-0253	3/2004	Pletz et al., Early Bactericidal Activity of Moxifloxacin in Treatment of Pulmonary Tuberculosis: a Prospective, Randomized Study,	BT002-009377-009379		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		Anti. Agents Chem., 48(3):780-82 (2004)			
PTX-0254	8/13/2003	Gosling et al., <i>The Bactericidal Activity of Moxifloxacin in Patients with Pulmonary Tuberculosis</i> , Am. J. Respir. Crit. Care Med., 168:1342-45 (2003)	BT002-009255-009258		None
PTX-0255	10/18/05	Press Release: TB Alliance and Bayer Launch Historic Global Drug Trials for Tuberculosis	Zhanel 114		None
PTX-0256		Collection of Bayer Data (with translation)	Zhanel 118		FRE 106 (incomplete document)
PTX-0257	7/11/1995	Pharma Report 24156	BL013-092913-092983		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0258	2/9/1994	Bayer Data (with translation)	BL002-021128; BL002-043209-043212		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0259	10/14/1994	Bayer Data (with translation)	BL002-043024-043027		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0260	1/17/1991	Bayer Data (with translation)	BL018-085170; BL002-094120-094121		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0261	9/20/1993	Minutes of AK-F Quinolone Meeting on 9/16/1993 (with translation)	BL002-096122-096132		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
					FRE 401/402/403 (irrelevant)  FRE 106 (incomplete document)  FRE 901/902 (authenticity as to data)
PTX-0262		Compound Card for BAY Y6957 (with translation)	BL002-015187		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0263	5/1993	Bayer Data (with translation)	BL002-051322-051340		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0264		Compound Card for BAY 12-8039 (with translation)	BL002-016090-016092		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0265	7/29/1993	Bayer Data (with translation)	BL002-020223; BL002-042046-042047		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0266	5/27/1993	Bayer Data (with translation)	BL002-020177; BL002-042167-042170		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0267	11/7/1995	Pharma Report 24451	BL013-059717-059766		None
PTX-0268	5/23/1995	Project Team Minutes—New Quinolones, May 3, 1995	BL005-043010-043031		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0269	10/27/1993	Bayer Data (with translation)	BL002-021038; BL002-043309		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0270		Bayer Data (with translation)	BL002-054001		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.  FRE 901/902 (authenticity as to data)
PTX-0271		Bayer Data (with translation)	BL002-093062		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.  FRE 901/902 (authenticity as to data)



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0272		Bayer Data (with translation)	BL002-093005-093006		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0273	1/16/1995	Pharma Report 23665	BL002-097006-097043		None
PTX-0274	6/28/1995	Project Team Minutes—New Quinolones, June 9, 1995	BL005-050929-050946		None
PTX-0275	7/21/1995	Project Team Minutes—New Quinolones, July 12, 1995	BL005-050912-050922		None
PTX-0276	9/19/2007	Responsive Expert Report of Dr. Eduardo Alfonso			FRE 801/802 (hearsay)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0277		Curriculum Vitae of Dr. Eduardo C. Alfonso	Alfonso 1		None
PTX-0277A	1/2008	Updated Curriculum Vitae of Dr. Eduardo C. Alfonso			None
PTX-0278	April 2002	Mather et al., <i>Fourth Generation Fluoroquinolones: New Weapons in the Arsenal of Ophthalmic Antibiotics</i> , Am. J. Ophthalmol., 133(4):463-66 (2002)	Alfonso 24		None
PTX-0279	2001	Drlica, <i>A Strategy for Fighting Antibiotic Resistance</i> , ASM News, 67(1) 27-33 (2001)	Alfonso 25		None
PTX-0280	11/2005	Silver et al., <i>Clinical Safety of Moxifloxacin Ophthalmic Solution 0.5% (Vigamox®) in Pediatric and Nonpediatric Patients with Bacterial Conjunctivitis</i> , Survey of Ophthalmology, 50(Suppl. 1):S55-S63 (2005)	Alfonso 26		None
PTX-0281	6/2007	Munir et al., <i>Clinical Response of Contact Lens-Associated Fungal Keratitis to Topical Fluoroquinolone Therapy</i> , Cornea 26(5):621-24 (2007)	Alfonso 29		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0282	2005	Alfonso and Miller, <i>Impact of 4th Generation Fluoroquinolones on Growth Rate and Detection Time of Fungal Pathogens</i> , Invest. Ophthalmology and Vis. Science, 46:2766-B319 (2005) (ARVO E-Abstract)	Alfonso 30		None
PTX-0283	9/1988	Lohr et al., <i>Comparison of Three Topical Antimicrobials for Acute Bacterial Conjunctivitis</i> , <i>Pediatr. Infect. Dis. J.</i> , 7(9):626-29 (1988)	Alfonso 33		None
PTX-0284	3/2004	Olson, <i>Challenges in Ocular Infectious Diseases and the Evolution of Anti-Infective Therapy</i> , <i>Survey Ophthalmology</i> , 49(Suppl. 2):S53-S54 (2004)	Alfonso 34		None
PTX-0285	12/1995	Endophthalmitis Vitrectomy Study Group, <i>Results of the Endophthalmitis Vitrectomy Study</i> , <i>Arch. Ophthalmol.</i> , 113:1479-96 (1995)	Alfonso 36		None
PTX-0286	12/1998	Montan et al., <i>Endophthalmitis After Cataract Surgery: Risk Factors Relating to Technique and Events of the Operation and Patient History: a Retrospective Case-Control Study</i> .	Alfonso 37		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		Ophthalmology, 105(12):2171-77 (1998)			
PTX-0287	5/1994	Lin et al., Comparative Efficacy of Topical Ciprofloxacin for Treating <i>Mycobacterium fortuitum</i> and <i>Mycobacterium chelonae</i> Keratitis in an Animal Model, Am J. Ophthalmol., 117(5):657-62 (1994)	Alfonso 38		None
PTX-0288	11/2005	McGee et al., Safety of Moxifloxacin as Shown in Animal and In Vitro Studies, Survey Ophthalmology, 50(Suppl. 1):S46-S54 (2005)	Alfonso 43		None
PTX-0289		Orange Book listing for Trovafloxacin	Alfonso 51		None
PTX-0290		Orange Book listing for Grepafloxacin	Alfonso 52		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0291	1998	Leophonte, <i>Trovafoxacin versus amoxicillin/clavulanic acid in the treatment of acute exacerbations of chronic obstructive bronchitis</i> , Eur. J. Clin. Microbiol. Infect Dis., 17(6):434-40 (1998)	Alfonso 54		None
PTX-0292	2007	Ohnsman et al., <i>Comparison of Azithromycin and Moxifloxacin Against Bacterial Isolates Causing Conjunctivitis</i> , Current Medical Research and Opinions, 23(9):2241-49 (2007)	Alfonso 56		FRE 401/402/403 (not provided with expert report)
PTX-0293	1994	Khooshabeh et al., <i>A Case Report of Mycobacterium chelonae Keratitis and a Review of Mycobacterial Infections of the Eye and Orbit</i> , Tubercle and Lung Disease, 75:377-82 (1994)	Alfonso 56A		None
PTX-0294	10/1995	Klapper et al., <i>Atypical Mycobacterial Infection of the Orbit</i> , Ophthalmology, 102(10):1536-41 (1995)	Alfonso 57		None
PTX-0295	3/1984	Newman et al., <i>A Cluster of Cases of Mycobacterium Chelonae Keratitis Associated with Outpatient Office Procedures</i> , Am. J. Ophthalmol., 97(3):344-48 (1984)	Alfonso 58		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0296	6/2001	Song et al., <i>Pseudomonas aeruginosa</i> In Vitro Corneal Isolate Sensitivity to Ofloxacin, Ciprofloxacin, and Trovafloxacin: A Comparative Study, Am. J. Ophthalmology, 131:795-96 (2001)	Alfonso 64		None
PTX-0297	2003	Kowalski et al., <i>The Prevention of Bacterial Endophthalmitis by Topical Moxifloxacin in a Rabbit Prophylaxis Model</i> , Invest. Ophthalmology and Vis. Science, 44:1467-B363 (2003) (ARVO E-Abstract)	Alfonso 71		None
PTX-0298	1992	Tripathi et al., <i>Cytotoxicity of Ophthalmic Preservatives on Human Corneal Epithelium</i> , Lens and Eye Toxicity Research, 9(3and4):361-75 (1992)	Alfonso 72		None
PTX-0299	5/5/2003	Kim et al., <i>Evaluation of the Effects of Topical Ophthalmic Fluoroquinolones (FQ) on the Cornea Using In Vivo Confocal Microscopy</i> , Invest. Ophthalmology and Vis. Science, 44:1367-B263 (2003) (ARVO E-Abstract)	Alfonso 73		None
PTX-0300	2005	Lee et al., <i>Fourth-Generation Fluoroquinolones in the Treatment of Mycobacterial Keratitis After Laser-Assisted In Situ Keratomileusis Surgery</i> , Can. J. Ophthalmol., 40(6):753-56 (2005)	Alfonso 74		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0301	11/2005	Alfonso and Crider, Ophthalmic Infections and Their Anti-infective Challenges, Survey of Ophthalmology, 50(Suppl. 1):S1-S6 (2005)	Alfonso 75		None
PTX-0302	2004	Abshire et al., Topical Antibacterial Therapy for Mycobacterial Keratitis Potential for Surgical Prophylaxis and Treatment, Clin. Ther. 26(2):191-96 (2004)	Alfonso 76		None
PTX-0303	9/19/2007	Responsive Expert Report of Dr. Ashim K. Mitra		DDX 109	FRE 801/802 (hearsay)
PTX-0304		Curriculum Vitae of Dr. Ashim K. Mitra		DDX 108	None
PTX-0305	1993	Lee, Precorneal, Corneal, and Postcorneal Factors, Ophthalmic Drug Delivery Systems, (Mitra ed.) Chapter 3: 59-59 (1993)	Mitra 02		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0306	1996	Reddy and Ganesan, Ocular Therapeutics and Drug Delivery: An Overview" in Ocular Therapeutics and Drug Delivery, (Reddy ed.) at 10-11 (1996)	Mitra 03		None
PTX-0307	1993	Hughes and Mitra, Overview of Ocular Drug Delivery and Latrogenic Ocular Cytopathologies, Ophthalmic Drug Delivery Systems, (Mitra ed.) at 1-5 (1993)	Mitra 05		None
PTX-0308	1989	Burstein, Basic Science of Ocular Pharmacology, Clinical Ocular Pharmacology, Second ed., Chapter 1 (1989)	Mitra 06		None
PTX-0309	1988	Narurkar and Mitra, Synthesis, Physicochemical Properties and Cytotoxicity Studies of a Series of Novel 5-Ester prodrugs of 5-Iodo-2'-Deoxyuridine, Pharm. Research, 5(11):734-37 (1988)	Mitra 07		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0310	1989	Narurkar and Mitra, <i>Prodrugs of 5-Iodo-2'-Deoxyuridine for Enhanced Ocular Transport</i> , Pharm. Research, 6(10):888-92 (1989)	Mitra 08		None
PTX-0311	1979	Mosher and Mikkelsen, <i>Permeability of the n-Alkyl p-Aminobenzoate Esters Across the Isolated Corneal Membrane of the Rabbit</i> , Int'l J. Pharm., 2:239-43 (1979)	Mitra 09		None
PTX-0312	6/1978	Schoenwald and Ward, <i>Relationship between Steroid Permeability across Excised Rabbit Cornea and Octanol-Water Partition Coefficients</i> , J. Pharm. Sci., 67(6):786-88 (1978)	Mitra 10		None
PTX-0313	1986	Jack, <i>Recent Advances in Pharmaceutical Chemistry. The 4-Quinolone Antibiotics</i> , J. Clin. Hosp. Pharm, 11:75-93 (1986)	Mitra 13A		None
PTX-0314	3/1986	Hirai <i>et al.</i> , <i>Differences in Susceptibility to Quinolones of Outer Membrane Mutants of Salmonella typhimurium and Escherichia coli</i> , Anti. Agents Chem., 29(3):535-38 (1986)	Mitra 13B		None
PTX-0315	4/1988	Chapman and Georgopapadakou, <i>Routes of Quinolone Permeation in Escherichia coli</i> , Anti.	Mitra 14		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		Agents Chem., 32(4):438-42 (1988)			
PTX-0316	12/1991	Nakanishi et al., <i>Mechanisms of Clinical Resistance to Fluoroquinolones in Staphylococcus aureus</i> , Anti. Agents Chem., 35(12): 2562-67 (1991)	Mitra 15		None
PTX-0317	1992	Ross et al., <i>Physicochemical Properties of the Fluoroquinolone Antimicrobials. III. 1-Octanol/Water Partition Coefficients and Their Relationships to Structure</i> , Int'l J. Pharm., 88:379-89 (1992)	Mitra 16		None
PTX-0318	5/10/1995	Fakuda and Sasaki, <i>In Vitro Topically Applied Fluoroquinolone Penetration into the Anterior Chamber</i> , J. Oph. Soc. Jap., 99(5):532-36 (1995)	Mitra 17		None
PTX-0319	1992	Takacs-Novak et al., <i>Lipophilicity of Antibacterial Fluoroquinolones</i> , Int'l J. Pharm., 79:89-96 (1992)	Mitra 18		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0320	1996	Montero et al., <i>Influence of Physicochemical Properties of Fluoroquinolones on Encapsulation Efficiency in Liposomes</i> , Int'l J. Pharm., 138:113-20 (1996)	Mitra 19		None
PTX-0321	2/1995	Zabinski et al., <i>Effect of Aerobic and Anaerobic Environments on Antistaphylococcal Activities of Five Fluoroquinolones</i> , Anti. Agents Chem., 39(2):507-12 (1995)	Mitra 20		None
PTX-0322	3/1997	Hämäläinen et al., <i>Characterization of Paracellular and Aqueous Penetration Routes in Cornea, Conjunctiva, and Sclera</i> , Invest. Oph. and Visual Science, 38(3):627-34 (1997)	Mitra 21		None
PTX-0323	6/1980	Lien and Wang, <i>Lipophilicity, Molecular Weight, and Drug Action: Reexamination of Parabolic and Bilinear Models</i> , J. Pharm. Sci., 69(6):648-50 (1980)	Mitra 22		None
PTX-0324	1994	Giasson and Bonanno, <i>Facilitated Transport of Lactate by Rabbit Corneal Endothelium</i> , Exp. Eye Res., 59:73-81 (1994)	Mitra 24		None
PTX-0325	1993	Stjernschantz and Astin, <i>Anatomy and Physiology of the Eye. Physiological Aspects of Ocular Drug Delivery</i> , Biopharmaceutics of Ocular Drug Delivery, (Edman ed.) Chapter 1 (1993)	Mitra 25		None
PTX-0326	8/1979	Stone, <i>The Transport of Para-Aminohippuric Acid by the Ciliary Body and by the Ins of the Primate</i>	Mitra 26		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		Eye. Invest. Oph. Vis. Sci., 18(8):807-18 (1979)			
PTX-0327	March/April 1998	Kawazu et al., <i>Corneal Permeability of the Quinolone Antibiotic Levofloxacin (LVFX)</i> , 118th Meeting of Pharmaceutical Society of Japan, Abstract 31[YB]10-1 (1998)	Mitra 27		None
PTX-0328	1999	Kawazu et al., <i>Characterization of the Carrier-mediated Transport of Levofloxacin, a Fluoroquinolone Antimicrobial Agent, in Rabbit Cornea</i> , J. Pharm. Pharmacol., 51:797-801 (1999)	Mitra 28		None
PTX-0329	1999	Kawazu et al., <i>Cultured Rabbit Corneal Epithelium Elicits Levofloxacin Absorption and Secretion</i> , J. Pharm. Pharmacol., 51:791-96 (1999)	Mitra 29		None
PTX-0330	6/1982	Barza et al., <i>The Effects of Infection and Probenecid on the Transport of Carbenicillin From the Rabbit Vitreous Humor</i> , Invest. Oph. Vis. Science, 22(6):720-26 (1982)	Mitra 30		None
PTX-0331	12/1983	Barza et al., <i>Pharmacokinetics of Intravitreal Carbenicillin, Cefazolin, and Gentamicin in Rhesus Monkeys</i> , Invest. Oph. Vis. Science, 24(12):1602-06 (1983)	Mitra 31		None
PTX-0332	1961	Becker and Forbes, <i>Iodopyracet (Diodrast) Transport by the Rabbit Eye</i> , Am. J. Physiol., 200(3):461-64 (1961)	Mitra 32		None
PTX-0333	1967	Cunha-Vaz and Maurice, <i>The Active Transport of Fluorescein by the Retinal Vessels and the</i>	Mitra 33A		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		Retina, J. Physiol., 191:467-86 (1967)			
PTX-0334	10/1979	Reddy, <i>Dynamics of Transport Systems in the Eye</i> , Friedenwald Lecture, Invest. Oph. Vis. Sci., 18(10):1000-18 (1979)	Mitra 33B		None
PTX-0335	6/1998	Saha et al., <i>Existence of a p-Glycoprotein Drug Efflux Pump in Cultured Rabbit Conjunctival Epithelial Cells</i> , Invest. Oph. Vis. Sci., 39(7):1221-26 (1998)	Mitra 34A		None
PTX-0336	7/1999	Kawazu et al., <i>Characterization of Cyclosporin A Transport in Cultured Rabbit Corneal Epithelial Cells: P-Glycoprotein Transport Activity and Binding to Cyclophilin</i> , Invest. Oph. and Vis. Science, 40(8):1738-44 (1999)	Mitra 34B		None
PTX-0337	1/1990	Freddo et al., <i>The source of Proteins in the Aqueous Humor of the Normal Rabbit</i> , Invest. Oph. Vis. Science, 31(1):125-37 (1990)	Mitra 35		None
PTX-0338	1996	Hughes et al., <i>Vitreous Disposition of Two Acycloguanosine Antivirals in the Albino and Pigmented Rabbit Models: A Novel Ocular Microdialysis Technique</i> , J. Ocul. Pharm. Ther., 12(2):209-24 (1996)	Mitra 36		None
PTX-0339	5/13/1993	Minutes of AK-F Quinolone Meeting on 3/19/1993 (with translation)	BL002-096188-096203		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
					accurate translation, if necessary.
PTX-0340	9/30/1993	Minutes of AK-F Quinolone Meeting on 9/16/1993 (with translation)	BL002-096143-096162		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0341	1/17/1995	Minutes of AK-F Quinolone Meeting on 11/20/1994 (with translation)	BL002-097044-097057		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0342		Compound Card for BAY Y3118 (with translation)	BL004-036010		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0343	7/26/1990	Bayer Data (with translation)	BL002-039513-039518		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
					accurate translation, if necessary.
					FRE 106 (incomplete document)
					FRE 403 (lack of translation)
PTX-0344		Collection of Bayer Data (with translation)	BL002-020194; BL002-020201-020202; BL002-020206; BL002-020223; BL002-046534		Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
					FRE 106 (incomplete document)
					FRE 403 (lack of translation)
PTX-0345		Collection of Bayer Data (with translation)	BL002-051341-051355; BL002-051356-051369; BL002-051387-051400		Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0346	3/10/1995	Pharma Report 23826	BL002-134026-134081		None
PTX-0347	1/8/1993	Status Report: AK Research "Quinolones" 1992	BL002-096056-096093		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0348	5/25/1992	Quinolone Project Meeting Minutes (with translation)	BL002-096324-096337		FRE 403 (lack of translation)  Teva reserves the right to object to Plaintiff's translation, or offer a more accurate translation, if necessary.
PTX-0349	11/30/1999	2000 Project Plan - Key Targets	AL001-000020-000029		None
PTX-0350		Avelox sales and market share data	BL021-000096-000106		None
PTX-0351		Avelox sales and market share data	BL021-000107-000113		None
PTX-0352		Avelox sales and market share data	BL021-000114-000118		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0353	7/6/2001	Email chain re: Cloxan and resistant strains	AL011-003743		None
PTX-0354	12/3/1999	Email chain re: Moxifloxacin ophthalmic solution toxicology supplies	AL020-002756-002757		None
PTX-0355	12/6/1999	Email chain re: Moxifloxacin concentration for toxicology and short term stability studies	AL015-001175-001178		None
PTX-0356	12/6/1999	Email chain re: Moxifloxacin concentration for toxicology and short term stability studies	AL020-002724-002727		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0357	9/3/1999	Email chain re: Moxifloxacin concentration for development	AL015-001267-001268		None
PTX-0358	11/15/1999	Email chain re: Moxifloxacin ophthalmic and otic prototype formulations	AL020-002655		None
PTX-0359	12/3/1999	Email from Schlech to team re: Moxifloxacin formulation concentration	AL018-000115		None
PTX-0360	12/9/1999	Email from Schlech to team re: Selection of the Concentration for a Global Moxifloxacin Product	AL015-001191-001192		None
PTX-0361	4/22/1999	Email from Stroman to Hiddemen and Schlech re: Moxifloxacin Advantages	AL001-006984-006985		None
PTX-0362	6/18/1999	Email from Stroman to Hiddemen re: antibiotic therapy needs	AL001-006763		None
PTX-0363	4/29/1999	Evaluation of Moxifloxacin HCl [BAY 12-8039] (AL-15469A)	AL003-000163-000279	DDX 073	None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0364		Excerpts form Alcon Laboratories Notebook # 10901	AL010-001000-001065		None
PTX-0365		Excerpts form Alcon Laboratories Notebook # 11030	AL010-002000-002025		None
PTX-0366		Excerpts form Alcon Laboratories Notebook # 13247	AL010-003000-003059		None
PTX-0367	11/13/1999	Excerpt from Lab Notebook 8324: One Day Topical Ocular Irritation/ Comfort Evaluation	AL007-003542-003543		FRE 106 (incomplete document)
PTX-0368	8/20/2001	Excerpt from Lab Notebook 9419: Kinetics of Kill- Moxifloxacin and Ciprofloxacin against p. aeruginosa	AL007-009740-009746		None
PTX-0369		Executive Summary	AL011-000012-000013		None
PTX-0370	3/30/1999	Letter and data from O'Callaghan to Stroman re: Moxifloxacin killing of Pseudomonas in rabbit intrastromal model of keratitis	AL011-003238-003241		FRE 801/802 (hearsay)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0371	11/29/1999	Letter and data from O'Callaghan to Stroman re: Moxifloxacin pre-treatment of Staph keratitis	AL011-003009-003011		FRE 801/802 (hearsay)
PTX-0372	4/9/2001	Letter and data from O'Callaghan to Stroman re: tests comparing Moxifloxacin and Ciloxan in the MRSA model of keratitis	AL011-003047-003049		FRE 801/802 (hearsay)
PTX-0373	3/22/2001	Letter and data from O'Callaghan to Stroman re: tests comparing Moxifloxacin and Ciloxan in the <i>Staphylococcus</i> model of keratitis	AL011-003035-003038		FRE 801/802 (hearsay)
PTX-0374	1/24/2001	Letter and data from O'Callaghan to Stroman re: tests comparing Moxifloxacin and Ciprofloxacin in late vs early treatment models of keratitis	AL011-003079-003081		FRE 801/802 (hearsay)
PTX-0378	12/11/1998	Moxifloxacin Meeting- Green Room	AL001-000487		FRE 901/902 (authenticity as to handwriting)
PTX-0379	2/4/2000	Moxifloxacin Ophthalmic Solution: January 2000 Report	AL001-000236-000238		None
PTX-0380	1/14/2000	Moxifloxacin Team Meeting Minutes	AL018-000090-000091		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0381	12/7/1999	Moxifloxacin Team Meeting Minutes-December 7, 1999	AL007-023932-023933		None
PTX-0382		"Pharmaceutical Development" (R&D Document)	AL020-007271-007272		FRE 106 (appears to be incomplete document)
PTX-0383		Opposition to EP 1117401 B1	AL002-000502-000774; AL002-010000; AL002-010052-010140		FRE 401/402/403 (irrelevant)
PTX-0384		Opposition Appeal to EP 1117401 B1	AL002-010000-0100051		FRE 402/402/403 (irrelevant)
PTX-0385	12/7/1999	Preliminary Preformulations Report	AL020-002827-002829		FRE 801/802 (hearsay) FRE 401/402/403 (irrelevant)
PTX-0386	2004	Robertson et al., <i>Absorption and Distribution of Moxifloxacin, Ofloxacin and Gatifloxacin into Ocular Tissues and Plasma Following Topical Ocular Administration to Pigmented Rabbits</i> (2004 ARVO Poster)	AL009-000001		FRE 403 (illegible document)
PTX-0387	2004	Robertson et al., <i>Absorption and Distribution of Moxifloxacin, Ofloxacin and Gatifloxacin into Ocular Tissues and Plasma Following Topical Ocular Administration to Pigmented Rabbits</i>	AL009-000002-000012		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
		(2004 ARVO Manuscript)			
PTX-0388	12/12/1999	Therapeutic Research - Annual Report – 1999	AL007-025109-025143		None
PTX-0389		Vigamox sales and market share data	AL019-000001		None
PTX-0390		Vigamox sales and market share data	AL019-000015-000071		None
PTX-0391		Vigamox sales and market share data	AL019-000072-000073		None
PTX-0392		Avelox Package Insert	BL021-000119-000149		None
PTX-0393		Vigamox Package Insert	AL002-000524A	DDX 110**	None
PTX-0394		Vigamox sales and market share data	AL019-000002		None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0395		Vigamox sales and market share data	AL019-000003-000014		None
PTX-0396	12/14/1998	Bayer's invoice for the first shipment of Moxifloxacin	AL001-004003		None
PTX-0397	12/31/1998	Customs brokers' invoice for the first shipment of Moxifloxacin	AL001-004002		None
PTX-0398		Executive Summary	AL011-000007		None
PTX-0399	10/21/1998	Letter from Alcon to Bayer requesting shipment of 10 grams of Moxifloxacin	AL001-004147		None
PTX-0400	11/12/1998	Letter from Bayer to Alcon notifying of the first shipment of Moxifloxacin	AL015-001285		FRE 106 (incomplete; attachments referenced in document not included)
PTX-0401		Moxifloxacin license agreement between Bayer and Alcon	AL006-000018-000059		None
PTX-0402	10/1/1998	Moxifloxacin screening agreement between Bayer and Nestle	AL001-004148-004154		None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-0403	12/7/2007	December 7, 2007 Letter from S. Fisher to D. Robinson re: Dr. Mitra's intent to rely on AL010-001000-001065; AL010-002000-002025; and AL010-003000-003059 at trial			None
PTX-1004	6/30/1989	EP 0350733 A2, Petersen et al., 7-(1-Pyrrolidinyl)-3-Quinolone- and -Naphthyridonecarboxylic Acid Derivatives, Method for Their Preparation and for Substituted Mono- and Bi-cyclic Pyrrolidine Intermediates, and Their Antibacterial and Feed Additive Compositions (Bayer)		DDX 004	None
PTX-1005	12/28/1992	EP 0550903 A1, Petersen et al., Quinolone and Naphthyridonecarboxylic Acid Derivatives as Antibacterial Agents (Bayer)		DDX 005	None
PTX-1025		Compound Card for BAY 11-6371 (with translation)	BL002-016182	DDX 025	None
PTX-1052	7/1/1993	Minutes of AK-F Quinolone Meeting on 6/9/1993 (with translation)	BL002-096166-096185	DDX 052	None
PTX-1053		Compound Card for BAY Y7575 (with translation)	BL002-014000; BL002-014014-014015	DDX 053	None
PTX-1058		Prosecution History for U.S.S.N. 08/026,906 (Teva Compilation)	FH026906-000005-140; FH026906-000145-146; FH026906-000149-157;	DDX 058	None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
			FH026906-000213-223		
PTX-1061	1997	Excerpt of Physicians' Desk Reference 51st Edition 1997: Alcon Ciloxan		DDX 061	None
PTX-1062	1997	Excerpt of Physicians' Desk Reference 51st Edition 1997: Alcon Tobradex		DDX 062	None
PTX-1063	1999	Excerpt of Physicians' Desk Reference 53rd Edition 1999: Alcon Ciloxan		DDX 063	None
PTX-1065	2/10/1998	Alcon's Research Compound Request for BAY 12-8039	AL001-003945	DDX 065	None
PTX-1066	2/9/1999	Weekly Status Report of Moxifloxacin Evaluation	AL001-000214-000215	DDX 066	None
PTX-1080	7/26/1990	Compound Card for BAY Y4196 (with translation)	BL002-015000; BL002-015256	DDX 080	None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-1092	3/3/1992	Pharma Report 21369	BL011-013756-013779	DDX 092	None
PTX-1095	9/1992	Snyder and Katz, <i>Ciprofloxacin-Resistant Bacterial Keratitis</i> , Am. Journal Ophthalmol. 114:336-38 (1992)		DDX 095	None
PTX-1096	7/1998	Forster, <i>The Management of Infectious Keratitis as We Approach the 21st Century</i> , CLAO Journal, 24(3):175-80 (1998)		DDX 096	None
PTX-1098	1996	Petersen et al., <i>Synthesis and in vitro Activity of BAY 12-8039, A New 8-Methoxyquinolone</i> , ICAAC (1996) (Poster F-001)	BL005-019300	DDX 098	None
PTX-1099	1997	Zurenko et al., <i>Oxazolidinone Antibacterial Agents: Development of the Clinical Candidates Eperzolid and Linezolid</i> , Expert Opin Investig Drugs, 6(2):151-58 (1997)		DDX 099	None
PTX-1100	2001	Ysasaga et al., <i>Efficacy of New Streptogramin (Synecrid) and Oxazolidinone (Linezolid) Antibiotics Against Vancomycin Reduced and Multi-Drug Resistant Staphylococci Recovered from Endophthalmitis Cultures</i> , Invest. Oph. Vis. Science, 42(4):1352-B665 (2001) (Abstract)		DDX 100	None
PTX-1101	Sept./Oct. 2003	Callegan et al., <i>Antibacterial Activity of the Fourth-Generation Fluoroquinolones Gatifloxacin and Moxifloxacin Against Ocular Pathogens</i> , Advances in Therapy, 20(5):246-52 (2003)		DDX 101	None

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-1102	2001	Rubinstein, <i>History of Quinolones and Their Side Effects</i> , Chemotherapy, 47(suppl. 3):3-8 (2001)		DDX 102	None
PTX-1107	5/28/2002	USPN 6,395,746 B1, Cagle et al., <i>Methods of Treating Ophthalmic, Otic and Nasal Infections and Attendant Inflammation</i> (Alcon)		DDX 107	None
PTX-1112	6/1974	Hull et al., <i>Permeability of the Isolated Rabbit Cornea to Corticosteroids</i> , Invest. Oph., 13(6):457-59 (1974)		DDX 112	None
PTX-1113	11/1983	Schoenwald and Huang, <i>Corneal Penetration Behavior of <math>\beta</math>-Blocking Agents I: Physicochemical Factors</i> , J. Pharm. Sci., 72(11):1266-72 (1983)		DDX 113	None
PTX-1114	6/1998	Liu et al., <i>Pharmacokinetics of Sparfloxacin in the Serum and Vitreous Humor of Rabbits: Physicochemical Properties That Regulate Penetration of Quinolone Antimicrobials</i> , Anti. Agents Chem., 42(6):1417-23 (1998)		DDX 114	None
PTX-1116		Alcon Data: <i>Ex Vivo Corneal Penetration of Fluoroquinolones</i>	AL007-038115-116	DDX 116	FRE 401/402/403 (irrelevant and not timely produced)
PTX-1117	2005	Solomon et al., <i>Penetration of Topically Applied Gatifloxacin 0.3%, Moxifloxacin 0.5%, and Ciprofloxacin 0.3% into the Aqueous Humor</i> , Ophthalmology 112 (3): 466-469 (March 2005)		DDX 117	None



TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-1118	9/2005	Wagner et al., <i>Evaluation of Moxifloxacin, Ciprofloxacin, Gatifloxacin, Ofloxacin, and Levofloxacin Concentration in Human Conjunctival Tissue</i> , Arch. Oph., 123:1182-83 (2005)		DDX 118	None
PTX-1119		Alcon Data: Corneal Perfusion Chambers- Moxifloxacin Rate of Diffusion (Flux)	AL007-038117-038120	DDX 119	FRE 401/402/403 (irrelevant and not timely produced)
PTX-1124	12/5/1996	Dalhoff et al., <i>In vitro Activity of BAY 12-8039, New 8-Methoxyquinolone</i> , Chemother., 42:410-25 (1996).		DDX 124	None
PTX-1125	1998	Schmitz et al., <i>Relationship between Ciprofloxacin, Ofloxacin, Levofloxacin, Sparfloxacin and Moxifloxacin (BAY 12-8039) MICs and Mutations in grlA, grlB, gyrA and gyrB in 116 Unrelated Clinical Isolates of Staphylococcus aureus</i> , J. Anti. Chem., 41:481-84 (1998).		DDX 125	None
PTX-1126	4/1998	Search Results: Table of contents, J. Antimicro. Chem., 41(4) (1998)		DDX 126	None
PTX-1133	6/2/2006	Letter from Teva Novopharm to Bayer re: Notice of Allegation and Detailed Statement Moxifloxacin Hydrochloride 400 mg Tablets	BL026-000001-000062	DDX 133	FRE 401/402/403 (irrelevant)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION	BATES RANGE/EXPERT EXHIBIT	DEPOSITION EXHIBIT NO.	Objections <sup>1</sup>
PTX-1134	3/8/2007	Notice of Appeal in the European Patent Office	AL002-010028-010047	DDX 134	FRE 401/402/403 (irrelevant)

\*\* DENOTES DIFFERENT VERSION OF THE SAME OR A SIMILAR DOCUMENT WAS A DEPOSITION EXHIBIT

# EXHIBIT 7



## DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S FIRST AMENDED TRIAL EXHIBIT LIST

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0001	02/05/1991	U.S. Patent No. 4,990,517		DDX 1	
DTX-0002	05/02/2001	U.S. Patent No. 6,235,908		DDX 2	R
DTX-0010	08/23/1988	Compound Card BAY W 8801, PEW 6431B (with certified translation) <sup>3</sup>	BL018-036000; BL018-036136	DDX 10	R
DTX-0011	01/16/1991	Status Report – AK Research Antibacterial Therapy 1990 (with certified translation)	BL003-001000; BL003-001005-001044	DDX 11	R
DTX-0014	3/6/1993	Compound card for PEW 76368 (with certified translation)	BL002-016190	DDX 14	Improper description, R
DTX-0018	02/12/1993	Compound card for BAY 12-8039 (with certified translation)	BL002-016090 - BL002-016092	DDX 18	

<sup>1</sup> Teva reserves the right to introduce evidence to show the publication date of any printed publication listed below, if necessary.

<sup>2</sup> As used in the foregoing objections, "R" refers to a relevance objection pursuant to Federal Rules of Evidence 401, 402, and 403; "H" refers to a hearsay objection pursuant to Federal Rules of Evidence 801, 802, and 805; "A" refers to an authenticity objection pursuant to Federal Rule of Evidence 901; "F" refers to an objection to lack of foundation pursuant to Federal Rules of Evidence 602 and 901; "Multiple Documents" refers to Federal Rules of Evidence 401, 402, 403, 1001, 1002, and 1003; "Inc." refers to incompleteness pursuant to Federal Rules of Evidence 106, 401, 402, and 403. By setting forth these objections to the documents on Teva's Trial Exhibit list, Plaintiffs do not concede that the descriptions of the documents on Teva's list are necessarily accurate. Plaintiffs reserve their right to object further to documents on or added to this list on any basis that depends upon how a document is introduced, for what purpose a document is introduced, and what portion of a document is introduced. In particular, pursuant to the Federal Rules of Evidence and the Court's practice, Plaintiffs object to the introduction of any exhibit to the extent it is not offered through the testimony of a witness. To the extent that the Court sustains any of Teva's objections to the introduction of an exhibit on Plaintiffs' Trial Exhibit list based on Teva's contention of untimely production, Plaintiffs reserve the right to object to any exhibit on Teva's Trial Exhibit list that was not timely produced.

<sup>3</sup> Teva has not produced most of the certified translations referenced on Teva's Exhibit List. Plaintiffs reserve the right to lodge any objection to the certified translations when they are produced.

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0020	11/23/1993	Compound Card BAY 12-7593, PEW 7769 (with certified translation)	BL002-016098	DDX 20	R
DTX-0022	09/24/1993	Compound Card BAY 11-9930, PEW 7746 (with certified translation)	BL002-016117	DDX 22	R
DTX-0024	08/25/1993	Compound Card BAY 11-8877, PEW 7701 (with certified translation)	BL002-016145	DDX 24	R
DTX-0025	16/6/1993	Compound card for BAY 11-6371 (with certified translation)	BL002-016182	DDX 25	
DTX-0026	7/5/1993	Compound card for PEW 7619 B (with certified translation)	BL002-016201	DDX 26	R
DTX-0027	25/3/1993	Compound card for PEW 7588 (with certified translation)	BL002-016223	DDX 27	R
DTX-0028	25/1/1989	Compound card for BAY X2893, with cover sheet (with certified translation)	BL002-012000, BL002-012063	DDX 28	R
DTX-0032	11/12/1990	Compound card for BAY Y6962, with cover sheet (with certified translation)	BL002-015000, BL002-015162	DDX 32	R
DTX-0034	11/23/1990	Compound Card BAY Y 6960, PEW 6979 (with certified translation)	BL002-015000; BL002-015167	DDX 34	R
DTX-0036	09/21/1990	Compound Card BAY Y 5655, PEW 6952 (with certified translation)	BL002-015000; BL002-015204-015205	DDX 36	R

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0037	7/9/1990	Compound card for BAY Y5039, with cover sheet (with certified translation)	BL002-015000, BL002-015221 - BL002-015222	DDX 37	R
DTX-0038	16/5/1990	Compound card for BAY Y3480, with cover sheet (with certified translation)	BL002-015000 BL002-015293	DDX 38	R
DTX-0040	18/5/1990	Compound cards for BAY Y3118, with cover sheet (with certified translation)	BL002-015000, BL002-015303 - BL002-015313	DDX 40	
DTX-0041	4/12/1989	Compound cards for BAY X8843, with cover sheet (with certified translation)	BL002-015000, BL002-015365 - BL002-015371	DDX 41	R
DTX-0042	24/11/1989	Compound card for BAY X8841, with cover sheet (with certified translation)	BL002-015000, BL002-015376, BL002-015377	DDX 42	R
DTX-0049	27/9/1990	Compound card with BAY Y5658, with cover sheet (with certified translation)	BL002-015000 BL002-015195 - BL002-015198	DDX 49	R
DTX-0051	4/10/1990	Compound card for BAY Y6957 (with certified translation)	BL002-014006	DDX 51	
DTX-0052	1/7/1993	Protokoll der Sitzung des AK- F "CHINOLONE" (with certified translation)	BL002-096166 - BL002-096185	DDX 52	
DTX-0056	12/02/1994	Excerpts from 5,607,942 File History (Declarations of Klaus- Dieter Bremm (12/02/1994 and 07/20/1995))	BT002-001505 and BT002- 001721-BT002- 001742 and BT002-002263	DDX 56	Inc.

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0057	12/7/2005	Certified File History of U.S. Patent No. 4,990,517	FH4990517- 000003 - FH4990517- 001218	DDX 57A -- DDX 57E	A,
DTX-0057A	12/7/2005	Certified file history of U.S. Patent No. 4,990,517	FH4990517- 000003 - FH4990517- 000214	DDX 57A	A, Inc.
DTX-0057B	12/7/2005	Certified file history of U.S. Patent No. 4,990,517	FH4990517- 000215 - FH4990517- 000403	DDX 57B	A, Inc.
DTX-0057C	12/7/2005	Certified file history of U.S. Patent No. 4,990,517	FH4990517- 000404 - FH4990517- 001030	DDX 57C	A, Inc.
DTX-0057D	12/7/2005	Certified file history of U.S. Patent No. 4,990,517	FH4990517- 001031 - FH4990517- 001162	DDX 57D	A, Inc.
DTX-0057E	12/7/2005	Certified file history of U.S. Patent No. 4,990,517	FH4990517- 001163 - FH4990517- 001218	DDX 57E	A, Inc.
DTX-0058	Multiple	File history of U.S Patent Application Serial No. 08/026,906	FH026906- 000001 - FH026906- 000280	DDX 58	A, Inc.
DTX-0059	6/1/2005	Certified File History of U.S. Patent No. 5,607,942	BT002-001505 - BT002-002263	DDX 59A -- DDX 59D	A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0059A	6/1/2005	Certified file history of U.S. Patent No. 5,607,942	BT002-001505 - BT002-001714	DDX 59A	A, Inc.
DTX-0059B	6/1/2005	Certified file history of U.S. Patent No. 5,607,942	BT002-001715 - BT002-001955	DDX 59B	A, Inc.
DTX-0059C	6/1/2005	Certified file history of U.S. Patent No. 5,607,942	BT002-001956 - BT002-002113	DDX 59C	A, Inc.
DTX-0059D	6/1/2005	Certified file history of U.S. Patent No. 5,607,942	BT002-002114 - BT002-002263	DDX 59D	A, Inc.
DTX-0060	6/19/2007	Plaintiff Alcon Manufacturing, Ltd.'s Response to Defendant's Notice of Deposition Pursuant to Fed. R. Civ. P. 30(b)(6)		DDX 60	R
DTX-0061	1997	Excerpt from the 51 <sup>st</sup> Edition of the Physician's Desk Reference (1997), pp. 468-469, with cover page, copyright information, and table of contents excerpt		DDX 61	
DTX-0062	1997	Excerpt from the 51 <sup>st</sup> Edition of the Physician's Desk Reference (1997), pp. 469-470, with cover page, copyright information, and table of contents excerpt		DDX 62	
DTX-0063	1999	Excerpt from the 53 <sup>rd</sup> Edition of the Physician's Desk Reference (1999), pp. 490-491, with cover page and copyright information		DDX 63	R



TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0064	9/18/1998	Email from Robert Abshire to Robert Hackett, Joe Hiddemen, and David Stroman	AL011-003419	DDX 64	R
DTX-0065	02/10/98	Alcon Research Compound Request	AL001-003945	DDX 65	A, F, R
DTX-0066	2/9/1999	Document entitled "Weekly Status of Moxifloxacin Evaluation as of February 9, 1999"	AL001-000214 - AL001-000215	DDX 66	
DTX-0067	9/15/1998	Handwritten communication from Jerry Cagle to R. Abshire and J. Yanni	AL002-002262 - AL002-002266	DDX 67	R
DTX-0068	4/20/2000	Email from Barry A. Schlech, Ph.D. having the subject "Moxifloxacin Team Meeting Minutes-Thu, April 20, 2000 [Training Room 10:30am]"	AL011-005383 - AL011-005386	DDX 68	
DTX-0069	6/24/1999	Email from Gerald D. Cagle to Joe Hiddemen, Stella Robertson, Rajni Jani, Barry Schlech, Ed Dorsey, Henry Baldwin, William Hubregs, Sudhir Dave, Tom McDonald, and Michael Bergamini	AL020-024622	DDX 69	R
DTX-0070	3/14/2003	Moxifloxacin Six Month Report-August 15, 2002-February 15, 2003	AL003-000378 - AL003-000387	DDX 70	R

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0071	12/4/2000	Email from Joe DeFaller to Lou DeSantis, Barry Schlech, David Stroman, Tom McDonald, Stella Robertson, Sally Yeager, and Glenda Johnson	AL020-052502	DDX 71	R
DTX-0072	6/12/2003	Email string having the subject "Moxifloxacin"	AL020-046600 - AL020-046602	DDX 72	M, R
DTX-0073	4/29/1999	"Evaluation of Moxifloxacin HCl [Bay 12-8039] (AL-15469A)"	AL003-000163 - AL003-000279	DDX 73	
DTX-0074	1997	Excerpt from the 51 <sup>st</sup> Edition of the Physician's Desk Reference (1997), pp. 478-479, with cover page and copyright information		DDX 74	
DTX-0075	Undated	Document entitled "Moxifloxacin's Greater Lipophilicity Results in Greater Penetration"	AL021-002351 - AL021-002352	DDX 75	A, R, H, F
DTX-0076	6/22/2003	Email with attachment from Evan Kyba to Stella Robertson	AL021-001106 - AL021-001109	DDX 76	R, H, F
DTX-0077	4/6/2004	Certified file history of U.S. Patent No. 6,716,830		DDX 77	
DTX-0078	9/22/1992	U.S. Patent No. 5,149,693		DDX 78	R
DTX-0079	2/18/2004	Email string having the subject "cornea donor project"	AL021-000424 - AL021-000429	DDX 79	F, R
DTX-0080	26/7/1990	Compound card for BAY Y4196, with cover sheet	BL002-015000, BL002-015256	DDX 80	



TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0081		EP 0 106 489 A2		DDX 81	Description missing date
DTX-0083	12/12/1989	Compound card BAY X8841	BL005-033345	DDX 83	R
DTX-0085		Excerpts from Notebook of Dr. Schenke (with certified translation)	BL018-122000-1 BL018-122291-93	DDX 85	R, no translation provided
DTX-0088	12/29/1989	Excerpts from Notebook of Dr. Schenke (with certified translation)	BL018-122000-1 BL018-122054-58	DDX 88	R
DTX-0090	00/00/1989	Excerpt from Petersen PEW 6731-6875 Binder (with certified translation)	BL008-011000 BL008-011335	DDX 90	R
DTX-0091	16/10/1992	Document entitled "Bay Y 3118 - eine hochwirksame Chinolonicarbonsäure mit einem neuen Wirkprofil," (with certified translation)	BL005-018000, BL005-018150 - BL005-018169	DDX 91	R
DTX-0092	03/03/1992	Bayer Report (with certified translation)	BL011-013756-79	DDX 92	R, no translation provided
DTX-0093	9/19/2007	Document entitled "Responsive Expert Report of Eduardo C. Alfonso, M.D."		DDX 93	
DTX-0094	7/26/2007	Document entitled "Expert Report of Dr. Loyd V. Allen, Jr."		DDX 94	H
DTX-0095	9/1992	<i>Snyder, et. al.</i> , Ciprofloxacin- resistant Bacterial Keratitis, Am. J. Ophthalm., 114:336-338 (September 1992)		DDX 95	A (handwriting)

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0096	7/1998	<i>Forster</i> , The Management of Infectious Keratitis As We Approach the 21 <sup>st</sup> Century, The CLAO Journal, Vol. 24, No. 3, pp. 175-180 (July 1998)		DDX 96	
DTX-0097	1996	Poster Entitled "Synthesis and In Vitro Activity of BAY12-8039, a New 8-Methoxyquinolone		DDX 97; DDX 111; DDX 123	F
DTX-0098	Undated	Poster Entitled "Synthesis and In Vitro Activity of BAY12-8039, a New 8-Methoxyquinolone	BL005-019300	DDX 98	F
DTX-0099	1997	<i>Zurenko, et al.</i> , Oxazolidinone antibacterial agents: development of the clinical candidates eperezolid and linezolid, Ex. Opin. Invest. Drugs (1997) 6(2): 151-158.		DDX 99	
DTX-0100	3/15/2001	<i>Ysasaga, et al.</i> , Efficacy of New Streptogramin(Synercid) and Oxazolidinone(Linezolid) antibiotics against Vancomycin Resistant and Multi-Drug Resistant Staphylococci recovered from Endophthalmitis cultures (Abstract)		DDX 100	

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0101	September/ October 2003	<i>Callegan, et al.</i> , Antibacterial Activity of the Fourth-Generation Fluoroquinolones Gatifloxacin and Moxifloxacin Against Ocular Pathogens, <i>Adv. Chemother.</i> 20(5): 246-252		DDX 101	
DTX-0102	2001	<i>Rubinstein</i> , History of Quinolones and Their Side Effects, <i>Chemother.</i> 2001; 47(suppl 3): 3-8, 44-46		DDX 102	
DTX-0103	10/29/2007	Internet page printout entitled "Search results from the 'OB_Rx' table for query on '019537'" (Orange Book records for Cipro)		DDX 103	R
DTX-0104	10/1998	<i>O'Brien et al.</i> , Topical Ciprofloxacin Treatment of Pseudomonas Keratitis in Rabbits, <i>Arch. Ophthalmol.</i> 106: 1444-1446		DDX 104	R
DTX-0105	Undated	Internet page printout entitled "Search results from the 'OB_Rx' table for query on '019735'" (Orange Book records for Floxin)		DDX 105	Incorrect title, R

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0106	1992	<i>Borrmann et al.</i> , Ofloxacin in Human Serum, Urine, and Tear Film After Topical Application, Cornea 11(3): 226-230		DDX 106	
DTX-0107	5/28/2002	U.S. Patent No. 6,395,746		DDX 107	R
DTX-0109	9/19/2007	"Responsive Expert Report of Ashim K. Mitra, Ph.D."		DDX 109	
DTX-0110	Undated	Product Insert for Vigamox®		DDX 110	
DTX-0112	6/1974	<i>Hull et al.</i> , Permeability of the isolated rabbit cornea to corticosteroids, Invest. Ophthalm. 13(6): 457-459		DDX 112	
DTX-0113	11/1983	<i>Schoenwald et al.</i> , Corneal Penetration Behavior of $\beta$ -Blocking Agents I: Physicochemical Factors, J. Pharm. Sci. 72(11): 1266-1272		DDX 113	
DTX-0114	6/1998	<i>Liu</i> , Pharmacokinetics of Sparfloxacin in the Serum and Vitreous Humor of Rabbits: Physicochemical Properties That Regulate Penetration of Quinolone Antimicrobials, Antimicrob. Agents Chemother. 42: 1417-1423		DDX 114	

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0115	2004	<i>Robertson et al.</i> , Absorption and Distribution of Moxifloxacin, Ofloxacin and Gatifloxacin into Ocular Tissues and Plasma Following Topical Ocular Administration to Pigmented Rabbits, Invest. Ophthalmol. Vis. Sci. 2004:45: E-Abstract 4906 (Abstract)		DDX 115	
DTX-0117	3/2005	<i>Solomon et al.</i> , Penetration of Topically Applied Gatifloxacin 0.3%, Moxifloxacin 0.5%, and Ciprofloxacin 0.3% into the Aqueous Humor, Ophthalmology 112(3): 466-469		DDX 117	
DTX-0118	9/2005	<i>Wagner et al.</i> , Evaluation of Moxifloxacin, Ciprofloxacin, Gatifloxacin, Ofloxacin, and Levofloxacin Concentrations in Human Conjunctival Tissue, Arch. Ophthalmol. 123:1282-1283		DDX 118	
DTX-0120	9/19/2007	"Responsive Expert Report of George G. Zhanel, Ph.D."		DDX 120	
DTX-0124	1996	<i>Dalhoff, et al.</i> , In vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone, Chemotherapy, 42:410-425 (1996)		DDX 124	

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0125	1998	<i>Schmitz et al.</i> , Relationship between ciprofloxacin, ofloxacin, levofloxacin, sparfloxacin, and moxifloxacin (BAY 12-8039) MICs and mutations in <i>griA</i> , <i>griB</i> , <i>gyrA</i> and <i>gyrB</i> in 116 unrelated clinical isolates of <i>Staphylococcus aureus</i> , J. Antimicrob. Chemother. 41:481-484 (1998)		DDX 125	
DTX-0126	04/1998	Table of contents for Volume 41, Number 4 of J. Antimicrob. Chemother.		DDX 126	R
DTX-0127	7/27/2007	"Expert Report of Edward C. Taylor, Ph.D."		DDX 127	
DTX-0128	9/19/2007	"Responsive Expert Report of Edward C. Taylor, Ph.D."		DDX 128	
DTX-0130	7/24/2007	"Expert Report of Professor Steven W. Baldwin"		DDX 130	R, H
DTX-0131	7/1984	Excerpt from Loudon, <u>Organic Chemistry</u> , pp. 212, 266, 267		DDX 131	
DTX-0133	6/2/2006	Letter from Brian DesIslet, Ph.D. to Bayer Inc., with attachments, re: Notice Of Allegation and Detailed Statement Moxifloxacin Hydrochloride 400 mg Tablets	BL026-000001 - BL026-000062	DDX 133	H

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0134	8/3/2007	Written statement setting out the grounds of appeal by Teva Pharmaceuticals Industries Ltd.; submitted to European Patent Office	AL002-010029 - AL002-010047	DDX 134	H
DTX-0135	4/15/2007	Curriculum Vitae of Loyd V. Allen, Jr., Ph.D.			
DTX-0136	2000	USP Dictionary of USAN and International Drug Names (2000 edition), p. 479			R
DTX-0137	2007	Excerpt from the 61 <sup>st</sup> Edition of the Physician's Desk Reference (2007), pp. 468-469, with cover page, copyright information, and table of contents excerpt			R
DTX-0138	1995	Remington: The Science and Practice of Pharmacy, 19 <sup>th</sup> ed. (1995), Ch. 89: Ophthalmic Preparations (author: Gerald Hecht), pp. 1563-1579 (Mack Publishing Co., Easton, Pa.)			
DTX-0139	1990	Modern Pharmaceuticals, 2 <sup>nd</sup> ed. (1990), Ch. 14: Design and Evaluation of Ophthalmic Pharmaceutical Products (Marcel Dekker, Inc., New York)			R



TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0140	1998	Tierney et al., eds., <u>Current Medical Diagnosis &amp; Treatment</u> , 37 <sup>th</sup> ed. (1998), pp. 186			R, F
DTX-0141	7/24/2007	Entry for "Ciloxan Solution/Drops; Ophthalmic" in the U.S. Food and Drug Administration's <u>Approved Drug Products with Therapeutic Equivalence Evaluations</u>			R
DTX-0142	1998	<i>Firestone et al.</i> , Solubility characteristics of three fluoroquinolone ophthalmic solutions in an in vitro tear model, Int. J. Pharm. 164:119-128 (1998)			R
DTX-0143	Undated	Abstract Entitled "Synthesis and In Vitro Activity of BAY12-8039, a New 8-Methoxyquinolone	BL014-011453		A, R
DTX-0144	1996	Excerpt from the 50 <sup>th</sup> Edition of the Physician's Desk Reference (1996), pp. 472-473, with cover page and copyright information			

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0145	1996	Excerpt from the 50 <sup>th</sup> Edition of the Physician's Desk Reference (1996), pp. 473-474, with cover page and copyright information			
DTX-0146	7/23/2007	Entry for "Ciloxan Ointment; Ophthalmic" in the U.S. Food and Drug Administration's <u>Approved Drug Products with Therapeutic Equivalence Evaluations</u>			R
DTX-0147		Curriculum Vitae of Professor Steven W. Baldwin			R
DTX-0148		Compound card for BAY X8842, with cover sheet	BL002-015000; BL002-015373 - 75		R
DTX-0149		Excerpt from Petersen PEW 6731-6875 Binder (with translations)	BL008-011000; BL008-011271 - 301		R
DTX-0150		Excerpt from Petersen PEW 6731-6875 Binder (with translations)	BL008-011000; BL008-011308 - 17		R
DTX-0151		Australian Patent Application No. AU-B-31054/93	BL022-008141 - 276		A, F, R
DTX-0152		New Zealand Patent Application No. 245640	BL022-016003 - 135		A, F, R
DTX-0153		CA 2 086 914		DDX 6	A, F, R

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0154	10/22/1991	US Patent No. 5,059,597 to Uwe Petersen, Thomas Schenke, Andreas Krebs, Klaus Grohe, Michael Schriewer, Ingo Haller, Karl G. Metzger, Rainer Endermann, and Hans-Joachim Zeiler			R
DTX-0155	10/22/1991	File history for US Patent Application No. 07/580,906 (issued as US Patent 5,059,597)			R
DTX-0156	5/16/1995	US Patent No. 5,416,096 to Uwe Petersen, Thomas Schenke, Andreas Krebs, Klaus Grohe, Michael Schriewer, Ingo Haller, Karl G. Metzger, Rainer Endermann, and Hans-Joachim Zeiler			R
DTX-0157	5/16/1995	File history for US Patent Application No. 07/737,631 (issued as US Patent 5,416,096)			R
DTX-0158	1/1997	<i>Woodcock et al.</i> , "In Vitro Activity of BAY 12-8039, a New Fluoroquinolone," Antimicrobial Agents and Chemotherapy, Jan. 1997, p. 101-106			

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0159	1995	Monograph for Ocuflux® from the 49 <sup>th</sup> edition of the Physicians' Desk Reference, pp. 496-497			
DTX-0160	1997	Adam, D. 1997 Influence of BAY 12-8039 on phagocytosis, burst, and killing (PKB) activities of human granulocytes. Abstract and Poster F-148, p 171.  <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-046154 - BC002-046156		F, A, R
DTX-0161	June 1998	Al-Nawas, B., Shah, P. 1998 Intracellular activity of ciprofloxacin and moxifloxacin, a new 8-methoxyquinolone, against methicillin-resistant <i>Staphylococcus aureus</i> .  J Antimicrob Chemother; 41:655-658.	BC002-046167 - BC002-046170		F, A, R

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0162	1996	Aldridge, K., Ashcraft, D. 1996 BAY 12-8039, a new 8-methoxyquinolone: <i>in vitro</i> activity against clinically important anaerobes. Abstract and Poster F-15, p 102.  <i>In</i> Program and abstracts of the 36 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BC002-046161 - BC002-046163		R, F, A
DTX-0163	March 1997	Aldridge, K., Ashcraft, D. 1997 Comparison of the <i>in vitro</i> activities of BAY 12-8039, a new quinolone, and other antimicrobials against clinically important anaerobes. 1997.  Antimicrob Agents Chemother. 41:709-711.	BC002-46158 - BC002-46160		

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0164	November 1997	Bauernfeind, A. 1997 Comparison of the antibacterial activities of the quinolones Bay 12-8039, gatifloxacin (AM 1155), trovafloxacin, cinafloxacin, levofloxacin and ciprofloxacin. <i>J Antimicrob Chemother.</i> 40:639-651.	BC002-046418 - BC002-046430		
DTX-0165	March 1998	Bebear, C., Renaudin, H., <i>et al.</i> 1998 <i>In vitro</i> activity of BAY 12-8039, a new fluoroquinolone, against mycoplasmas. Antimicrob Agents Chemother. 42:703-704.	BC002-046432 - BC002-046433		
DTX-0166	June 1997	Boswell, F., Andrews, J., Wise, R. 1997. Pharmacodynamic properties of BAY 12-8039 on gram-positive and gram-negative organisms as demonstrated by studies of time-kill kinetics and postantibiotic effect. Antimicrob Agents Chemother. 41:1377-1379.	BC002-046510 - BC002-046512		

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0167	1997	Brenwald, N., Gill, M., Wise, R. 1997. Fluoroquinolone resistance in <i>Streptococcus pneumoniae</i> by an efflux mechanism. Abstract and poster C181, p 77. In Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-046521 - BC002-046523		R, F, A
DTX-0168	July 1997	Brueggemann, A., Kugler, K., Doern, G. 1997. <i>In vitro</i> activity of BAY 12-8039, a novel 8-methoxyquinolone, compared to activities of six fluoroquinolones against <i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i> , and <i>Moraxella catarrhalis</i> . <i>Antimicrob Agents Chemother.</i> 41:1594-1597.	BC002-046554 - BC002-046557		



TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0169	1997	Dalhoff, A. 1997. Dissociated resistance among fluoroquinolones. Abstract 3257, p 90. <i>In Program and abstracts of the 20<sup>th</sup> International Congress of Chemotherapy, Sydney, Australia.</i>	BC002-046564		R, F, A
DTX-0170	1998	Dalhoff, A. 1998. Lack of <i>in vivo</i> emergence of resistance against BAY 12- 8039 in <i>S. aureus</i> and <i>S. pneumonia</i> . Abstract and poster 47.003, p124. <i>In</i> Abstracts of the 8 <sup>th</sup> International Congress on Infectious Diseases, Boston, Massachusetts.	BC002-046616 - BC002-046619		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0171	1997	Durham, E., Amyes, G., <i>et al.</i> 1997. <i>In vitro</i> activity of BAY 12- 8039 against <i>Staphylococcus</i> <i>aureus</i> . Abstract and Poster F-139, p 169. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-046688 - BC002-046690		R, F, A
DTX-0172	1998	Everett, M., Piddock, L. 1998. Mechanisms of resistance to fluoroquinolones. <i>In</i> : Kuhlmann, J., Dalhoff, A., Zeiler, H., J. eds. Quinolone Antibacterials, Berlin, Springer Verlag; p 259-296.	BC002-046691 - BC002-046728		R, F, A
DTX-0173	August 1997	Fass, R. 1997. <i>In vitro</i> activity of BAY 12- 8039, a new 8- methoxyquinolone. Antimicrob Agents Chemother. 41:1818-1824.	BC002-046729 - BC002-046735		

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0174	1996	Felmingham, D., Robbins, M., <i>et al.</i> 1996. <i>In vitro</i> activity of BAY 12-8039 against bacterial respiratory tract pathogens, mycoplasmas and obligate anaerobic bacteria. Abstract, F-8, p 101. <i>In</i> Program and abstracts of the 36 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BC-046847		R, F, A
DTX-0175	1997	Felmingham, D., Robbins, M., <i>et al.</i> 1997. <i>In vitro</i> activity of BAY 12-8039. Abstract & Poster. P1156, p285. <i>In</i> Program and abstracts of the 8 <sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases, Lausanne, Switzerland.	BC002-046844 - BC002-046846		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0176	1998	Gillespie, S., Billington, O. 1998. Activity of BAY 12-8039 against mycobacteria. Abstract and Poster 55.021, p 176. <i>In Abstracts of the 8<sup>th</sup> International Congress on Infectious Diseases, Boston, Massachusetts.</i>	BC002-047017 - BC002-047020		R, F, A
DTX-0177	July 1997	Goldstein, E., Citron, D., <i>et al.</i> 1997. <i>In vitro</i> activity of BAY 12- 8039, a new 8- methoxyquinolone, compared to the activities of 11 other oral antimicrobial agents against 390 aerobic and anaerobic bacteria isolated from human and animal bite wound skin and soft tissue infections in humans. <i>Antimicrob Agents Chemother.</i> 41:1552-1557.	BC002-047021 - BC002-047026		

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0178	1997	Gross, W., Vadney, F., <i>et al.</i> 1997. <i>In vitro</i> activity of BAY 12-8039, a new 8-methoxyquinolone, against mycobacteria. Abstract and Poster F-144, p 170. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-047027 - BC002-047029		R, F, A
DTX-0179	1998	Grosset, J., Lounis, N., <i>et al.</i> 1998. <i>In vitro</i> and <i>in vivo</i> activities of moxifloxacin and clinafloxacin against <i>Mycobacterium tuberculosis</i> . Abstract and Poster 55.014, p 175. In Abstracts of the 8 <sup>th</sup> International Congress on Infectious Diseases, Boston, Massachusetts.	BC002-047030 - BC002-047033		

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0180	1997	Heisig, P., Wiedemann, B. 1997. <i>In vitro</i> activity of the new quinolone BAY 12-8039 against defined mutants of <i>Escherichia coli</i> and <i>Staphylococcus aureus</i> . Abstract and Poster F-140, p 169. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-047034 - BC002-047036		R, F, A
DTX-0181	1996	Jacobs, E., Dalhoff, A., Brunner, H. 1996. Efficacy of BAY 12-8039 in <i>Mycoplasma pneumoniae</i> infected guinea pigs. Abstract and Poster F-17, p 102. <i>In</i> Program and abstracts of the 36 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BC002-047145 - BC002-047147		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0182	August 1998	Ji et al., 1998  In vitro and in vivo activities of moxifloxacin and clinafloxacin against Mycobacterium tuberculosis.  Antimicrob Agents Chemother. 42(8):2066-9.			R, F, A
DTX-0183	1997	Kenny, G., Cartwright, F. 1997. Susceptibilities of human mycoplasma to BAY 12- 8039.  Abstract and Poster F-143, p 170. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-047155 - BC002-047157		R, F, A



TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0184	1996	Kitzis, M., Goldstein, F., <i>et al.</i> 1996. <i>In vitro</i> activity of BAY 12-8039 against multiply-resistant <i>Staphylococcus aureus</i> , <i>Streptococcus pneumoniae</i> and <i>Enterococcus faecalis</i> . Abstract and Poster F-12, p 102. <i>In</i> Program and abstracts of the 36 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BC002-047158 - BC002-047160		R, F, A
DTX-0185	December 1997	Klugman, K., Capper, T. 1997. Concentration-dependent killing of antibiotic-resistant pneumococci by the methoxyquinolone moxifloxacin. J Antimicrob Chemother. 40:797-802.	BC002-047161 - BC002-047166		

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0186	1996	Kubitza, D., Stass, H., <i>et al.</i> BAY 12-8039, a new 8- methoxy-quinolone: Safety, tolerability and steady state of pharmacokinetics in healthy male volunteers.  Intersci Conf Antimicrob Agents Chemother, New Orleans, Louisiana, 1996, 104 Abstr F25.	BC002-075109		R, F, A
DTX-0187	October 1997	MacGowan, A., Bowker, K. <i>et al.</i> 1997. Bay 12-8039, a new 8- methoxy-quinolone: comparative in-vitro activity with nine other antimicrobials against anaerobic bacteria.  <i>J Antimicrobial Chemother.</i> 40:503-509.	BC002-047174 - BC002-047180		

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0188	1997	Maggiolo, F., Capra, R., <i>et al.</i> 1997. Subinhibitory concentrations of BAY 12-8039, pharmacodynamic effect <i>in vitro</i> . Abstract & Poster. F-147, p 171. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-047182 - BC002-047184		R, F, A
DTX-0189	1996	Nichterlein, T., Kretschmar, M., Hof, H. 1996. BAY 12-8039, a new quinolone derivative is superior to standard therapeutics in murine salmonellosis and listeriosis. Abstract and Poster F-14, p 102. <i>In</i> Program and abstracts of the 36 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BC002-047412 - BC002-047413		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0190	1997	Nishino, T., Gotoh, Y., Otsuki, M. 1997. <i>In vitro</i> and <i>in vivo</i> antibacterial activity of BAY 12-8039, a new quinolone. Abstract and Poster 3352, p 108. <i>In</i> program and abstracts of the 20 <sup>th</sup> International Congress of Chemotherapy, Sydney, Australia.	BC002-047414 - BC002-047416		R, F, A
DTX-0191	1997	Ostergaard, C., Sorensen, T., <i>et al.</i> 1997. Evaluation of a new 8-methoxyquinolone – BAY 12-8039 – against a penicillin-resistant <i>Streptococcus pneumoniae</i> type 9V in experimental meningitis in rabbits. Abstract and poster B77, p 40. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-047420 - BC002-047423		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0192	1997	Pong, A., Thomson, K., <i>et al.</i> 1997. Activity of BAY 12-8039 against staphylococcal and pneumococcal mutants with diminished susceptibility or resistance to ciprofloxacin. Abstract and Poster C-85, p 61. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-047440 - BC002-047442		R, F, A
DTX-0193	1996	Renaudin, H., Bebear, C., <i>et al.</i> 1996. <i>In vitro</i> activity of BAY 12- 8039, a new fluoroquinolone against <i>Mycoplasma</i> . Abstract, F-9, p 101. <i>In</i> Program and abstracts of the 36 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BX002-047446		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0194	1997	Rouse, M., Piper, K., <i>et al.</i> 1997. <i>In vitro</i> and <i>in vivo</i> activity of ciprofloxacin, levofloxacin, sparfloxacin or BAY 12-8039 against penicillin-resistant <i>Streptococcus pneumoniae</i> . Abstract and Poster B-3, p 26. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-047460 - BC002-047462		R, F, A
DTX-0195	June 1998	Schmidt, H., Dalhoff, A., <i>et al.</i> 1998. Moxifloxacin in the therapy of experimental pneumococcal meningitis. Antimicrob Agents Chemother. 42:1397-1401.	BC002-047472 - BC002-047476		

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0196	1998	Schmitz, F., Verhoef, J., et al. 1998. <i>In vitro</i> activity of various antimicrobials against 194 unrelated clinical methicillin- resistant <i>Staphylococcus</i> <i>aureus</i> (MRSA) isolates and stability of MIC values in 125 clonally related clinical MRSA.  Abstract and poster 13.007, p 22. <i>In Abstracts of the 8<sup>th</sup></i> International Congress of Infectious Diseases, Boston, Massachusetts.	BC002-047485 - BC002-047488		R, F, A
DTX-0197	1996	Stass, H., Dalhoff, A., <i>et al.</i> BAY 12-8039, a new methoxyquinolone: First pharmacokinetic results in healthy male volunteers.  Abstracts selected from the 36. ICAAC by Bayer, New Orleans, Louisiana, 1996, 27 Abstr F024.	BX002-075016		Improper description



TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0198	August 1998	Stass, H., Dalhoff, A., <i>et al.</i> Pharmacokinetics, safety and tolerability of ascending single doses of moxifloxacin, a new 8-methoxy quinolone, administered to healthy subjects. <i>Antimicrob Agents Chemother</i> , 1998, 42:2060-2065.	BC002-075026 - BC002-075031		R, F, A
DTX-0199	1998	Stass, H., Halabi, A., <i>et al.</i> No dose adjustment needed for patients with renal impairment receiving oral BAY 12-8039. Intersci Conf Antimicrob Agents Chemother, San Diego, California, 1998, 4 Abstr A-14.	BC002-075042		R, F, A
DTX-0200	1997	Stass, H., Kubitza, D., <i>et al.</i> BAY 12-8039 does not interact with theophylline. Int Congr Chemother ICC, Sydney, Australia, 1997, 108 Abstr 3356.	BC002-075021		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0201	1997	Stass, H., Kubitza, D., <i>et al.</i> BAY 12-8039, a new 8- methoxy-quinolone: Pharmacokinetics, safety and tolerability of single ascending intravenous doses in healthy male volunteers. 37 Intersci Conf Antimicrob Agents Chemother, Toronto, Ontario, Canada, 1997, 172 Abstr F-153.	BC002-075035		R, F, A
DTX-0202	1997	Stass, H., Kubitza, D., <i>et al.</i> Pharmacokinetics, safety and tolerability of 800 mg BAY 12-8039 administered orally as a single dose. 8 Eur Congr Clin Microbiol Inf Dis, Lausanne, Switzerland, 1997, Abstr p 388.	BC002-075025		R, F, A
DTX-0203	1997	Stass, H., Schuehly, U., <i>et al.</i> Pharmacokinetics, safety and tolerability of 600 mg BAY 12-8039 administered once daily over 10 days. Clin Microbiol Infect 3, Eur Congr Clin Microbiol, Lausanne, Switzerland, 1997, 87 Abstr p 387.	BC002-075032		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0204	1997	Sullivan, J., Woodruff, M., <i>et al.</i> Pharmacokinetics and tolerability of the new methoxyquinolone BAY 12-8039: 10 days treatment at 400 mg daily. 8 Eur Congr Clin Microbiol Inf Dis, Lausanne, Switzerland, 1997, Abstr p 389.	BC002-075024		R, F, A
DTX-0205	1997	Tarasi, A., Monaco, M., <i>et al.</i> 1997. Activity of BAY 12-8039 (B) in combination with vancomycin (V) or teicoplanin (T) against <i>S. aureus</i> (SA) isolated from infections unresponsive to glycopeptides (G). Abstract and Poster F-141, p 170. <i>In</i> Program and abstracts of the 37 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Canada.	BC002-047511 - BC002-047513		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0206	1996	Thomson, K., Backes, S., Sanders, C. 1996. Susceptibility to BAY 12-8039 of pneumococci and staphylococci with varying levels of ciprofloxacin resistance.  Abstract and Poster F-16, p 102. <i>In</i> PROGRAM AND ABSTRACTS OF THE 36 <sup>TH</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BC002-047514 - BC002-047516		R, F, A
DTX-0207	1996	Vesga, O., Conklin, R., <i>et al.</i> 1996. Pharmacodynamic activity of BAY 12-8039 in animal infection models.  Abstract and Poster F-22, p 102. <i>In</i> Program and abstracts of the 36 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BC002-047595 - BC002-047606		R, F, A

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0208	1996	Waterbury, K., Wang, J., <i>et al.</i> 1996. Efficacy of BAY 12-8039, a potent new quinolone in mouse models of typical and atypical respiratory infection.  Abstract and Poster F-18, p 102. <i>In</i> Program and abstracts of the 36 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, Louisiana.	BC002-047622 - BC002-047623		R, F, A
DTX-0209	June 1998	Zhan, G., Karlowsky, J., Hoban, D. 1998. <i>In vitro</i> activities of six fluoroquinolones against Canadian isolates of vancomycin-sensitive and vancomycin-resistant <i>Enterococcus</i> species.  Diag Microbiol Infect Dis; 31:343-347.	BC002-047731 - BC002-047735		R, F, A
DTX-0210	12/09/1998	Bayer Letter to FDA re NDA 21-085	BC002-000003 - 05		R, F, A
DTX-0211		Index to Bayer's NDA 21-085 (50-764)	BC002-000022 - 162		R

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-0212		Compact Disc containing the Abstracts from the 1995, 1996, and 1997 Interscience Conferences on Antimicrobial Agents and Chemotherapy (with jewel box insert)			Not produced, H, A, F.
DTX-1003	3/4/1997	U.S. Patent No. 5,607,942		PDX 3	
DTX-1005	4/6/2004	U.S. Patent No. 6,716,830		PDX 5	
DTX-1007	04/09/2007	Notice of Deposition Pursuant to Fed.R.Civ.P.30(b)(6)		PDX 7	
DTX-1011	11/01/2005	Teva: Section IV-RX/OTC Statement; Requirements for 314.94(a)(4) Through (6)	T000028-0031	PDX 11	
DTX-1012		Teva: Section V.3 - Labeling: Labeling Comparison (Side By Side Comparison)	T000059-0073	PDX 12	
DTX-1018	11/05/2005	Teva: Section VIII.1 - Raw Materials Controls: Active Ingredient	T000107-0177	PDX 18	
DTX-1020		US Patents Assigned to Bayer/Alcon: 6,548,079 B1; 6,916,484 B1; 6,740,664 B2; 6,716,830 B2;	T005279-5307	PDX 20	
DTX-1065	11/29/2004	Section XV.3 Analytical Methods: Methods Validation - RR-Isomer Content by Chiral HPLC	T000822-843	PDX 65	
DTX-1066	10/10/2003	Specification & Method of Analysis (HPLC analytical methods of Dr. Reddy's)	DRLMOX 000457-60	PDX 66	

TRIAL EXHIBIT NO.	DATE	DESCRIPTION <sup>1</sup>	BATES RANGE	DEPOSITION EXHIBIT NO.	OBJECTION(S) <sup>2</sup>
DTX-2002		Certified Copy of Prosecution History of USPN 4,990,517	BT002-000061 - 1450		
DTX-2004		Certified Copy of Prosecution History of USPN 5,607,942	BL020-001721 - 2479		
DTX-2013	1/21/1986	Statusbrief 1985 - AKF “Antibakterielle Therapie” (D13) (with certified translation)	BL002-100310 - 43		
DTX-2022		Demonstrative in Reddy’s Case	BT002-013513		
DTX-2058		Demonstrative in Reddy’s Case	BT002-013516		
DTX-2071-A		Demonstrative in Reddy’s Case	BT002-013518		
DTX-2073		Demonstrative in Reddy’s Case	BT002-013520		
DTX-2079		Dr. Petersen’s Notebook PEW 6876-7000	BL008-012000 – BL008-012469		R
DTX-2163	11/17/2005	Certified Copy of EP App. No. 0195316 A1, Irikura, et al., Quinolonecarboxylic Acid	RT001-012950 - 93		Incorrect description
DTX-2223		Pages from Sprung Horn’s patent Files re: abandoned 08/026,906 prosecution history	SH_000001-004967 - 8; SH_000001-005103 - 27; SH_000001-005129 - 63; SH_000001-005169-223		Incomplete





# EXHIBIT 8

**EXHIBIT 8**

**WITNESSES PLAINTIFFS MAY CALL AT TRIAL**

Bayer and Alcon set forth below the names and addresses of the witnesses whom they intend to call to testify at trial, either in person or by deposition, a brief statement of the specialties of the expert witnesses whom Plaintiffs intend to call, and a list of designations for the witnesses who will testify by deposition. Witnesses for whom the address provided is “c/o Bayer” or “c/o Alcon” may be contacted through litigation counsel for Bayer and Alcon. If any witness listed as a person who Bayer and Alcon intend to call to testify in person is unavailable, Plaintiffs reserve the right to offer deposition testimony from such witness. Plaintiffs also may call any witnesses listed by Teva, and reserve the right to call additional witnesses in rebuttal to those witnesses called by Teva.

As discussed further below, Plaintiffs’ expert witnesses will testify concerning scientific principles and issues disclosed in their respective expert reports and deposition testimony. In addition, consistent with the parties’ proposed stipulation, Plaintiffs will serve an interrogatory response on or before January 21, 2008 setting forth any additional subjects of expert testimony that relate to Teva’s defenses that the ‘830 patent is invalid under 35 U.S.C. § 112.

**A. Witnesses Whom Plaintiffs Intend to Call to Testify in Person**

1. Uwe Petersen  
c/o Bayer
2. Peter Bailly  
c/o Bayer
3. Klaus-Dieter Bremm  
c/o Bayer
4. Peter Fey  
c/o Bayer

5. Kurt G. Briscoe  
Norris McLaughlin & Marcus, P.A.  
875 Third Avenue  
18th Floor  
New York, NY 10022
6. David Stroman  
c/o Alcon
7. Kathleen Alford  
c/o Alcon
8. Gregg Brown  
c/o Alcon
9. Witnesses to authenticate Bayer and/or Alcon documents, things, or exhibits, if necessary
10. Edward Taylor, Ph.D.  
Princeton University  
Frick Chemical Laboratory  
Washington Road  
Princeton, NJ 08544

Professor Taylor is an expert in medicinal chemistry and drug discovery, and will testify concerning scientific principles and issues disclosed in his expert reports and deposition testimony. Dr. Taylor reserves the right to testify as to any opinions set forth therein and to respond to assertions made by Teva's experts.

11. George Zhanel, Ph.D.  
Department of Medical Microbiology  
Faculty of Medicine, University of Manitoba  
MS673 Microbiology, Health Sciences Centre  
820 Sherbrook Street  
Winnipeg, Manitoba, Canada R3A 1R9

Dr. Zhanel is an expert in microbiology, medical microbiology, and pharmacology of antiinfectives, including quinolones, and will testify concerning scientific principles and issues disclosed in his expert report and deposition testimony. Dr. Zhanel reserves the right to testify as to any opinions set forth therein and to respond to assertions made by Teva's experts.

12. Dr. Eduardo Alfonso  
Bascom-Palmer Eye Institute  
University of Miami  
900 N.W. 17th Street  
Miami, FL 33136

Dr. Alfonso is an expert in ophthalmology, microbiology, and the treatment of ophthalmic infections, and will testify concerning scientific principles and issues disclosed in his expert reports and deposition testimony. Dr. Alfonso reserves the right to testify as to any opinions set forth therein and to respond to assertions made by Teva's experts.

13. Ashim Mitra, Ph.D.  
Division of Pharmaceutical Sciences  
School of Pharmacy  
University of Missouri  
5005 Rockhill Road, Room 108C  
Kansas City, MO 64110

Dr. Mitra is an expert in ocular drug delivery and the ocular pharmacokinetics of topical ophthalmic compositions, and will testify concerning scientific principles and issues disclosed in his expert report and deposition testimony. Dr. Mitra reserves the right to testify as to any opinions set forth therein and to respond to assertions made by Teva's experts.

14. Daniel W. Armstrong, Ph.D.  
University of Texas - Arlington  
Department of Chemistry & Biochemistry  
700 Planetarium Place Room 114 CPB  
Arlington, TX 76019

Dr. Armstrong has expertise in chemistry and particular expertise in the separation, detection, and purification of enantiomers, as well as other aspects of analytical chemistry. He will testify concerning scientific principles and issues disclosed in his expert report and deposition testimony. Dr. Armstrong reserves the right to testify as to any opinions set forth therein and to respond to assertions made by Teva's experts.

**B. Witnesses Whom Bayer and Alcon Intend to Call to Testify by Deposition**

1. Paul Fackler\*\*  
 c/o Teva Pharmaceuticals USA, Ltd.  
 1090 Horsham Road  
 P.O. Box 1090  
 North Wales, PA 19454-1090

<u>Deposition Designations</u>	<u>Objections</u>
5:19-22	
5:24-7:8	
7:19-18:14	
20:10-16	
20:22-21:10	
21:17-22:6	
22:9-11	
22:21-23:17	
23:20-24:18	
24:21-25:4	
25:7-12	
25:22-28:6	
28:9-16	
28:19-22	
29:24-30:20	
35:1-15	
35:22-37:15	
37:18-24	
38:3-39:7	

<u>Deposition Designations</u>	<u>Objections</u>
46:11-47:4	
48:1-50:12	
51:4-55:7	
55:10-56:9	
56:11-57:10	
57:23-58:2	
58:5	
58:7-11	
58:14-20	
58:23-59:15	
61:18-62:8	
63:24-65:24	
66:3-5	
71:7-73:8	
74:23-75:21	
82:4-7	
82:10-21	
83:7-8	
83:11-19	
83:22-84:12	
86:18-87:1	
87:4-14	
88:15-17	



<b><u>Deposition Designations</u></b>	<b><u>Objections</u></b>
88:20-89:6	
89:9-17	
89:20-90:1	
92:21-93:16	
93:19-95:7	
96:3-14	
96:23-97:1	
97:5-10	
99:1-100:8	
100:11-21	
101:1-7	
101:23-102:5	
103:3-104:5	
104:8-105:1	
105:24-109:7	
109:10-114:2	
114:4-10	
115:16-23	
116:3-118:16	
118:19-121:16	
121:19-21	
121:24-122:14	
122:17-123:22	

<u>Deposition Designations</u>	<u>Objections</u>
124:1-7	
124:10-17	
124:20-125:7	
125:21-127:6	
130:4-24	
131:13-135:7	
135:10-21	
136:10-138:7	
139:23-140:4	
140:8-141:5	
141:19-143:13	
143:22-144:7	
144:10-19	
144:22	
145:10-148:14	
148:18-149:2	
149:5-6	
149:9-10	
151:6-152:23	
153:20-154:20	

2. Anna Faingersh  
c/o Teva Pharmaceuticals Industries Ltd.  
ISRAEL

<u>Deposition Designations</u>	<u>Objections</u>
5:9-11	
5:15-19	
6:3-25	
7:2-14	
7:19-21	
7:25	
8:2-6	
9:18-20	
9:23-25	
10:2-6	
11:17-22	
14:21-22	
15:10-14	
15:18-25	
16:2-15	
16:18-23	
27:22-25	
28:2-11	

28:15	
39:14-25	
40:2-15	
47:13-25	
48:2-5	
48:17-24	
49:17-20	
50:5	
50:20-25	
58:12-25	
59:2-6	
64:7-21	
65:7-16	
65:20-21	
65:25	
66:2-6	
66:22-25	
67:2-7	
83:6-14	

84:7-25	
85:2-4	
88:11-15	
89:5-18	
92:13-23	
93:2-22	
94:4-7	
96:23-25	
97:4-6	
97:8-19	
97:24-25	
98:3-6	
98:8	
98:12-13	
98:15-17	
98:23-25	
99:2-5	
99:8-25	
100:2-8	

103:21-25	
104:2-7	
105:12-19	
107:13-16	
107:18-21	
108:7-10	
108:23-25	
109:2-6	
124:9-16	

3. Mali Kadosh  
c/o Teva Pharmaceuticals Industries Ltd.  
ISRAEL

<u>Deposition Designations</u>	<u>Objections</u>
4:12-15	
5:21-23	
6:2-15	
8:8-14	
9:3-4	
12:8-14	
12:23-25	
13:2-7	
13:11-16	

<u>Deposition Designations</u>	<u>Objections</u>
13:21-25	
14:2-7	
24:22-25	
25:2-10	
25:14-18	
26:2-3	
26:5	
26:10-17	
26:25	
27:2-5	
27:8-16	
31:9-16	
47:12	
47:14-19	
47:25	
48:2-19	
48:22-23	
49:5-9	
49:12-16	
50:10-18	
50:24	
51:7-16	
51:19-21	



<u>Deposition Designations</u>	<u>Objections</u>
51:24	
60:18-20	
60:23-25	
61:2-7	
61:11-15	
65:24-25	
66:2-4	
68:3-11	
75:6-9	
82:11-18	
83:22-24	
84:7-8	
84:10	
100:25	
101:2-4	
101:7-21	
127:20-23	
127:25	
128:2-24	
131:18-19	
131:24-25	
132:2-10	
132:15-17	

<b><u>Deposition Designations</u></b>	<b><u>Objections</u></b>
132:19-21	
132:23	
151:15-24	
155:15-16	
156:3-4	
156:7-11	
160:18-25	
161:2	
162:4-6	
162:8-15	
163:11-25	
164:4-14	
164:17-22	
164:24-25	
165:2-14	
165:16-23	
166:25	
167:2-4	
167:6	
181:19-22	
183:3-4	
183:7-20	
186:11-21	

4. Anne Payne\*\*  
 c/o Teva Pharmaceuticals USA, Ltd.  
 1090 Horsham Road  
 P.O. Box 1090  
 North Wales, PA 19454-1090

<u>Deposition Designations</u>	<u>Objections</u>
7:19-8:1	
8:10-17	
8:21-22	
9:3-9	
9:12-19	
10:6-25	
11:4-12:5	
16:7-18:21	
19:3-20:25	
21:4-22	
28:6-20	
30:12-25	
32:5-33:3	
33:6-12	
33:15-34:5	
34:8-35:2	
35:5-24	
37:21-38:21	
42:12-23	

<u>Deposition Designations</u>	<u>Objections</u>
48:18-49:16	
50:3-51:8	
53:18-54:3	
54:11-18	
54:21-55:20	
56:2-5	
56:12-58:14	
58:18-20	
60:4-18	
64:13-16	
64:19-65:8	
66:19-23	
67:1-11	
68:4-69:3	
70:11-25	
71:3-8	
72:15-73:6	
74:18-20	
74:24-75:12	
75:20-23	
80:14-84:10	
89:4-6	
89:9-92:4	

<u>Deposition Designations</u>	<u>Objections</u>
92:22-97:7	
97:10-98:15	
98:18-99:6	
99:9-102:11	
106:4-7	
106:10-109:3	
109:6-111:16	
111:22-112:12	
112:15-23	
113:1-2	
114:16-117:8	
117:11-120:2	
128:4-131:3	
131:6-133:2	
133:5-8	
151:9-152:13	
156:12-23	

In addition, to the extent any witnesses identified above testified as witnesses pursuant to Rule 30(b)(6), Defendants may call Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. to testify by deposition.

\*\* If Plaintiffs are for some reason unable to introduce the deposition testimony of Mr. Fackler or Ms. Payne, Plaintiffs may call them to testify live.

# EXHIBIT 9

**EXHIBIT 9**

**THIRD AMENDED LIST OF WITNESSES TEVA MAY CALL AT TRIAL**

Teva sets forth below the names and addresses of the witnesses whom Teva intends to call to testify at trial, either in person or by deposition, and a brief statement of the specialties of the expert witness whom Teva intends to call. Witnesses for whom the address provided is “c/o Teva” may be contacted through litigation counsel for Teva. If any witness listed as a person who Teva intends to call to testify in person is unable to testify live at trial, Teva reserves the right to offer deposition testimony from such witness. Teva may also call any witnesses listed by Plaintiffs, and reserves the right to call additional witnesses in rebuttal to those witnesses called by Plaintiffs.

As further discussed below, Teva’s experts will testify concerning scientific principles and issues disclosed in their respective expert reports and deposition testimony.

**I. Witnesses Whom Teva Intends To Call To Testify In Person**

1. Loyd V. Allen, Jr., Ph.D.  
International Journal of Pharmaceutical Compounding  
122 N. Bryant  
Edmond, OK 73034

Dr. Allen is an expert in pharmaceuticals. He will testify as to the level of ordinary skill in the art with respect to the ‘830 patent as of September 1998, and the anticipation and obviousness of claim 1 of the ‘830 patent. Dr. Allen’s opinions are set forth in more detail in his expert report and deposition testimony, and he reserves the right to testify as to any opinions set forth therein and to respond to assertions made by Alcon’s experts.

2. Steven W. Baldwin  
Professor of Chemistry  
Duke University  
1101 French Family Science Center  
124 Science Drive  
Durham, NC 27708



## Exhibit 9: Witnesses Teva May Call At Trial

Dr. Baldwin is an expert in synthetic organic and bio-organic chemistry. He will testify as to scientific principles relating to stereochemistry, including the stereochemistry of moxifloxacin. Dr. Baldwin's opinions with respect to principles of stereochemistry are set forth in more detail in his expert report and deposition testimony. He reserves the right to testify as to these opinions, and to respond to assertions made by Plaintiffs' experts.

3. Plaintiffs and Teva have agreed that since Dr. Bremm and Dr. Petersen are expected to appear live at trial that Teva need not present deposition designations for either witness. The parties are expected to present a stipulation for approval by the court as to the examination of each witness.

## II. Witnesses Whom Teva Intends To Call To Testify By Deposition

1. Dr. Uwe Petersen<sup>1</sup>  
c/o Bayer

Deposition Designations	Objections
5:3-19	
6:10-15	
6:18-20	
7:5-8:15	
8:21-25	
9:5-9	

---

<sup>1</sup> Plaintiffs object to each and every designation of Dr. Uwe Petersen's testimony on the grounds of hearsay. The parties have agreed that Plaintiffs may lodge other objections to Teva's designation of Dr. Petersen's testimony and counterdesignate testimony after the PreTrial Conference in a timely manner and with reasonable notice to Teva, in the event that the Court overrules Plaintiffs' hearsay objection.

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
9:15-18	
9:20-22	
11:3-8	
11:10-15	
11:17-20	
11:22-25	
12:2-7	
12:9-10	
12:12-21	
13:14-18	
14:22-15:6	
15:10-11	
15:13-16:25	
17:2-8	
17:10-18:19	
18:24-19:7	
19:10-15	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
19:17-20	
19:22-20:9	
20:11-13	
20:16-17	
20:19-25	
21:2-4	
21:13-17	
21:19-25	
22:2	
23:8-24:19	
25:2-4	
25:6-9	
25:11-15	
30:8-31:10	
31:12-31:20	
31:22-23	
32:1-4	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
32:16-34:20	
34:23-36:1	
36:3	
36:9-11	
36:13-37:13	
37:15-38:8	
38:10-17	
38:19-22	
38:24-39:3	
39:5-22	
40:6-18	
40:20-41:1	
41:3-9	
41:11-14	
41:17-24	
42:1-5	
42:8-10	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
42:12-43:8	
63:24-64:3	
64:7-19	
64:21-65:8	
65:10-25	
66:1-9	
66:13-15	
66:17-24	
70:19-71:1	
71:4-13	
71:15-19	
71:23-25	
72:2-3	
72:5-23	
72:25-73:6	
73:18-75:9	
75:14-24	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
76:10-13	
77:5-6	
77:8-9	
78:16-17	
78:20-79:7	
79:9	
79:18-19	
79:21-80:17	
80:19-81:5	
81:7-82:7	
82:11-83:13	
83:16-84:17	
84:19-85:8	
85:10-25	
86:2-13	
86:15-87:2	
87:11-88:5	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
88:18-89:6	
89:8-17	
89:20-90:1	
90:9-12	
90:15-24	
91:1-2	
91:4-11	
92:1-3	
92:12-16	
93:14-94:12	
95:7-12	
95:15-17	
95:19-96:3	
96:5-97:4	
97:6-12	
97:14-98:2	
98:4-14	



## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
140:24-144:2	
144:4-10	
145:2-146:15	
146:21-147:11	
147:13-17	
147:19-25	
154:16-20	
154:22-155:4	
155:6-12	
155:18-156:9	
156:11-18	
157:13-23	
157:25-158:10	
158:12-13	
158:19-159:3	
170:1-171:12	
171:17-173:20	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
174:11-12	
174:23-175:3	
175:6-14	
175:19-176:9	
176:12-15	
176:17-18	
176:20-177:19	
177:21-178:2	
178:5-8	
178:10-14	
178:17-179:4	
179:7-12	
179:17-180:4	
180:6-10	

<b>Trial Testimony Designations (Bayer v. Dr. Reddy's Labs.)</b>	<b>Objections</b>
238:16-22	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Trial Testimony Designations (Bayer v. Dr. Reddy's Labs.)</b>	<b>Objections</b>
239:1-15	
240:3-15	
243:3-5	
243:16-244:1	
244:23-25	
245:9-13	
246:4-16	
249:5-10	
251:1-5	
251:12-252:9	
253:11-15	
253:25-254:19	
255:4-7	
268:13-18	
296:2-297:3	
299:4-9	
306:3-15	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Trial Testimony Designations (Bayer v. Dr. Reddy's Labs.)</b>	<b>Objections</b>
306:19-307:5	
312:25-313:2	
313:12-314:10	
314:17-315:9	
315:13-316:3	
322:13-323:8	
324:9-11	
327:6-328:5	
353:2-21	
354:11-16	
376:25-377:8	
378:2	
378:5-11	
378:20-21	
379:12-15	
383:10-16	
391:5-8	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Trial Testimony Designations (Bayer v. Dr. Reddy's Labs.)</b>	<b>Objections</b>
441:21-24	
445:10-25	
446:3-10	
446:17-22	
448:3-450:2	
466:3-21	

2. Kurt G. Briscoe  
Norris McLaughlin & Marcus, P.A.  
875 Third Avenue  
18<sup>th</sup> Floor  
New York, NY 10022

<b>Deposition Designations</b>	<b>Objections</b>
5:1 - 6:1	
6:16 - 19	
7:2 - 7:4	
8:11 - 8:17	
9:2 - 9:3	
9:5 - 9:7	
11:3 - 11:9	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
11:19 - 13:17	
15:25 - 16:25	
17:20 - 18:17	
19:4 - 19:8	
19:14 - 19:21	Incomplete.
23:13 - 25:19	
26:10 - 26:16	
26:18 - 27:13	
27:15 - 27:19	
28:5 - 28:19	
31:22 - 33:22	
33:23 - 34:16	
34:20 - 35:13	
37:14 - 37: 19	
37:22 - 37:25	
38:10 - 39:23	
42:10 - 42:12	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
43:20 - 45:3	
45:11 - 45:12	
45:17 - 48:12	
48:19 - 49:8	
49:22 - 50:12	
50:19 - 53:22	

3. Peter Fey  
c/o Bayer

<b>Deposition Designations</b>	<b>Objections</b>
32:6-33:4	Relevance
47:17-48:4	Relevance

4. David Stroman  
c/o Alcon

<b>Deposition Designations</b>	<b>Objections</b>
6:1-15	
7:15-8:7	Incomplete
9:11-11:17	
12:3-13:12	



## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
13:23-25	
14:7-16:17	
16:24-17:7	
18:6-20:7	
20:10-21:13	
22:24-27:5	
28:19-30:3	
31:5-32:7	
32:12-35:6	
35:15-37:18	Incomplete
38:2-22	
39:12-40:3	
40:11-46:6	Incomplete
47:9-48:10	Incomplete
48:25-49:2	
49:7-51:14	
52:3-54:10	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
54:12-55:5	
55:10-56:8	
56:19-57:11	
58:13-59:2	
64:23-65:15	
66:4-66:13	
66:21-68:19	Incomplete
69:10-71:9	
71:21-73:1	
76:2-79:4	
79:7-80:2	
80:12-19	
81:1-18	
82:5-83:16	
84:18-85:2	
85:9-13	
85:25-87:8	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
87:12-89:4	
89:19-90:15	Incomplete
92:11-93:10	
93:21-94:17	
95:15-97:18	
98:13-102:1	
102:13-103:15	
106:9-108:3	
108:5-110:5	
110:19-112:13	
112:23-116:9	
116:16-21	Incomplete
118:25-121:6	
122:7-122:20	
123:6-8	
127:20-128:6	
128:17-128:25	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
129:4-10	
129:18-24	
130:7-14	
131:3-134:15	
134:21-136:21	
136:25-138:9	
138:15-140:2	
140:20-141:11	
141:24-142:15	
143:8-11	
143:14-144:13	
144:17-145:12	
146:4-147:21	
149:2-152:8	
153:3-162:18	
165:1-166:4	
169:5-12	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
169:22-170:3	
170:9-14	
170:19-22	
171:6-25	Incomplete
172:9-175:6	
175:9-13	
178:8-14	
178:18	
178:21-179:6	
179:22-182:7	
182:11-14	
182:20-183:13	
184:1-189:4	
189:6-191:15	
193:5-8	
193:18-195:13	
195:18-20	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
195:22-25	
196:1-198:13	
198:19-199:3	
199:8-203:13	
204:5-205:19	
205:21-207:24	
208:10-209:3	
209:7-12	
209:14-210:12	
212:16-18	
213:1-2	
213:25-214:9	
216:17-226:1	
226:14-18	
227:20-228:15	

**Plaintiffs' Counterdesignations:**

30:14-31:4

32:8-11

35:7-13

## Exhibit 9: Witnesses Teva May Call At Trial

37:23-38:1  
 46:7-47:6  
 60:9-61:7  
 62:24-64:2  
 64:15-22  
 69:3-9  
 73:2-16  
 74:25-75:8  
 75:21-76:1  
 80:20-25  
 90:16-21  
 116:10-15  
 129:25-130:6  
 166:18-167:15  
 210:13-212:15  
 228:16-18

5. George Zhanel, Ph.D. (Adversely on the § 112 issues)  
 Department of Medical Microbiology  
 Faculty of Medicine, University of Manitoba  
 MS673 Microbiology, Health Sciences Center  
 820 Sherbrook Street  
 Winnipeg, Manitoba, Canada R3A 1R9

Deposition Designations	Objections
4:4-12	Hearsay
4:21-7:9	Hearsay
19:4-20:24	Hearsay
81:25-83:4	Hearsay
85:11-91:18	Hearsay
91:22-93:13	Hearsay
94:16-95:6	Hearsay



## Exhibit 9: Witnesses Teva May Call At Trial

6. Dr. Eduardo Alfonso (Adversely on the § 112 issues)  
 Bascom-Palmer Eye Institute  
 University of Miami  
 900 N.W. 17<sup>th</sup> Street  
 Miami, FL 33136

Deposition Designations	Objections
5:4-14	
12:10-17:13	Hearsay
17:15-20:7	Hearsay
24:21-25:13	Hearsay
25:20-26:20	Hearsay
26:25-27:6	Hearsay
27:7-27:11	Hearsay
27:14-28:18	Hearsay
29:7-31:16	Hearsay
31:25-33:1	Hearsay
51:6-25	
52:4-53:4	
53:8-24	
54:4-15	
54:19-56:2	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations</b>	<b>Objections</b>
56:5-25	
57:21-58:21	
59:2-9	
60:7-17	
60:19-20	
61:11-64:8	
73:17-73:22	Hearsay
73:25-75:12	Hearsay
76:3-76:6	Hearsay
76:11-77:1	Hearsay
77:5-78:22	Hearsay
80:7-80:10	Hearsay
80:15-80:20	Hearsay

## Exhibit 9: Witnesses Teva May Call At Trial

7. Ashim Mitra, Ph.D. (Adversely on the § 112 issues)  
 Division of Pharmaceutical Sciences  
 School of Pharmacy  
 University of Missouri-Kansas City  
 5005 Rockhill Road, Room 108C  
 Kansas City, MO 64110

<b>Deposition Designations</b>	<b>Objections</b>
4:4-14	
4:18-6:16	Hearsay
47:2-50:7	Hearsay
50:11-52:16	Hearsay
52:20-53:23	Hearsay
53:25-56:3	Hearsay
64:25-66:16	Hearsay
69:4-9	Hearsay
69:14-70:8	Hearsay
70:25-71:13	Hearsay
73:14-74:13	Hearsay
204:15-205:16	Hearsay

If Teva is for some reason unable to introduce the deposition testimony of any of the individuals listed above, Teva may call them to testify live.

## Exhibit 9: Witnesses Teva May Call At Trial

**III. Designations, Counter-Designations And Objections To Plaintiffs' Designations**

As counter-designations, Teva includes all of Plaintiffs' designations and also the following.

1. Paul Fackler  
c/o Teva Pharmaceuticals USA, Inc.

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
45: 7-15	
57: 11-22	
62:17 - 63:2	
66: 9- 19	
66: 24 - 67:5	
69: 18 - 70:3	Relevance; Speculation
70: 19 - 71:6	
75: 22 - 76:4	Relevance; Speculation
76: 20 - 77:18	Relevance; Speculation
82: 22 - 83:1	
83: 4-6	
96: 15-22	Relevance; Speculation
97: 2-4	

## Exhibit 9: Witnesses Teva May Call At Trial

97: 11-17	
98: 7-12	Relevance
98: 15-22	Relevance

**Plaintiffs' Additional Designations:**

67:6-67:24

2. Anna Faingersh  
c/o Teva Pharmaceuticals USA, Inc.

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
55:19-21	
67:8-25	
68:2-25	
69:2-25	
70:2-25	
71:2-25	
72:2-25	
73:2-25	
74:2-25	
75:2-25	
76:3-25	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
77:2-13	
77:17-25	
78:2-25	
79:2-4	
79:9-25	
80:2-25	
81:3-9	
81:11-25	
82:2-11	
82:24-25	
83:2-5	
87:3-24	
88:2-4	
88:16-25	
89:2-4	
89:19-24	
90:12-15	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
90:19-25	
91:2	
91:7-10	
91:18-24	
94:11-12	
94:16-25	
95:2-13	Incomplete
95:20-25	
96:19-22	
100:20-22	
100:24-25	
101:2-6	
101:11-25	Relevance
102:2-4	Relevance
103:10-13	Relevance
103:15-20	Relevance
104:8-12	



## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
104:14-16	
109:7-19	Relevance

**Plaintiffs' Additional Designations:**

102:5-9

109:20-21

109:23-25

3. Mali Kadosh  
c/o Teva Pharmaceuticals USA, Inc.

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
4:12-15	
14:14-25	
15:2-7	
18:12-22	
22:18-24	
26:18-24	
27:17-20	
27:23-25	
28:2-3	Mistake
48:24-25	
49:2-4	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
56:18-24	
57:22-25	
58:2-10	
61:8-10	
61:23-25	
62:2-9	
62:11-12	
70:8-15	
71:12-25	Incomplete; Relevance
72:2	Incomplete; Relevance
133:25	Relevance
134:2-5	Relevance
134:11-12	Relevance
134:14-25	Relevance
135:2-25	Relevance
136:2-5	Relevance
136:8-16	Relevance

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
136:22-25	Relevance
137:2-25	Relevance
138:2-25	Relevance
139:2-25	Relevance
140:2-16	Relevance
155:17-25	
156:12-25	
157:2-15	
159:9-25	
161:6-11	
161:17-22	
161:24-25	
162:2-3	
165:24-25	
166:3	
187:12-13	Relevance
187:18-22	Relevance

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
187:25	Relevance
188:2-5	Relevance
191:14-17	Relevance
191:22-25	Relevance
193:7-8	Relevance; Incomplete; Calls for a Legal Conclusion
193:16-19	Relevance; Incomplete; Calls for a Legal Conclusion
193:22	Relevance; Incomplete; Calls for a Legal Conclusion
194:2-3	Relevance; Incomplete; Calls for a Legal Conclusion
194:8-11	Relevance; Incomplete; Calls for a Legal Conclusion
194:15-18	Relevance; Incomplete; Calls for a Legal Conclusion
194:20-21	Relevance; Incomplete; Calls for a Legal Conclusion

**Plaintiffs' additional designations:**

15:8-18  
 56:25  
 57:2-3  
 57:12-15  
 62:13-15  
 161:12-16  
 166:6-8  
 188:6-14  
 188:16-24  
 189:4-10  
 193:9-14  
 193:20-21  
 193:23-25  
 194:4-7

## Exhibit 9: Witnesses Teva May Call At Trial

196:13-14

4. Anne Payne  
c/o Teva Pharmaceuticals USA, Inc.

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
21:23 - 22:3	
22:14 - 22:18	
24:4 - 24:7	
25:16 - 26:16	
30:4 - 30:11	
31:13 - 31:25	Foundation; Speculation
35:25 - 36:14	Hearsay
54:4 - 54:7	
58:15 - 58:17	
73:7 - 73:19	
76:20 - 77:1	Foundation; Speculation
77:7 - 77:9	
86:20 - 87:7	
88:15 - 88:16	
88:18 - 88:25	

## Exhibit 9: Witnesses Teva May Call At Trial

<b>Deposition Designations/Counter-Designations</b>	<b>Objections</b>
89:2 - 3	
102:12 - 102:20	
104:22 - 105:9	
109:4 - 109:5	
111:19 - 111:20	Incomplete

**Plaintiffs' additional designations:**

102:21-103:1

# EXHIBIT 10



**EXHIBIT 10**

**PLAINTIFFS' BRIEF STATEMENT OF INTENDED PROOFS**

**I. INFRINGEMENT**

1. The drug product that is the subject of Teva's ANDA No. 77-437 infringes each of claims 1, 2, 8, and 9 of the '517 patent and each of claims 1, 2, 3, and 4 of the '942 patent.

2. The use of the drug product that is the subject of Teva's ANDA No. 77-437 in accord with any label submitted in Teva's ANDA No. 77-437 infringes each of claims 1, 2, 8, 9, and 11 of the '517 patent and each of claims 1, 2, 3, 4, 5, and 7 of the '942 patent.

3. The drug product that is the subject of Teva's ANDA No. 78-073 infringes each of claims 1, 2, and 8 of the '517 patent, each of claims 1, 2, 3, and 4 of the '942 patent, and claim 1 of the '830 patent.

4. The use of the drug product that is the subject of Teva's ANDA No. 78-073 in accord with any label submitted in Teva's ANDA No. 78-073 infringes each of claims 1, 2, 8, and 11 of the '517 patent, each of claims 1, 2, 3, 4, 5, and 7 of the '942 patent, and claim 1 of the '830 patent.

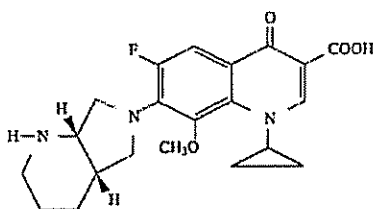
**II. CLAIM CONSTRUCTION**

1. The asserted claims of the '517 patent encompass any compound defined by the structural formulas presented in the claims—*i.e.*, any compound possessing the connectivity of atoms set forth in the claims, without limitation to a particular stereochemistry, including all stereoisomers, individually or any combination thereof. The claims are not limited to a racemic or diastereomeric mixture.

2. The phrase “substantially free” as used in claims 1, 3, and 5 of the '942 patent means “largely, but not necessarily free.”

3. Claims 2, 4, and 7 of the '942 patent encompass any compound defined by the structural formulas presented in the claims—*i.e.*, any compound possessing the connectivity of atoms set forth in the claims, without limitation to a particular stereochemistry, including all stereoisomers, individually or any combination thereof. The claims are not are not limited to a racemic or diastereomeric mixture.

4. The term “moxifloxacin” as used in claim 1 of the '830 patent has the well known, common, and ordinary meaning that a person of ordinary skill attributed to that term, specifically a compound having the following structure:



A person of ordinary skill in the art would not have understood the patentee to have re-defined the well-known term moxifloxacin in a manner that deviates from the common, ordinary meaning.

### III. DOUBLE PATENTING

Plaintiffs do not bear the burden of proof on double patenting. To the extent necessary, Plaintiffs will establish sufficient grounds to defeat Teva's allegations of double patenting for the '942 patent, including as follows:

1. The asserted claims of the '942 patent are not invalid for obviousness-type double patenting over claim 1, claim 2, claim 4, or claim 5 of the '517 patent.
2. The asserted claims of the '942 patent are not *prima facie* invalid for obviousness-type double patenting over claim 1, claim 2, claim 4, or claim 5 of the '517 patent.

3. The asserted claims of the '942 patent are patentably distinct from claim 1, claim 2, claim 4 and claim 5 of the '517 patent.

4. The invention claimed in the asserted claims of the '942 patent possesses unexpected desirable results.

5. Objective indicia of non-obviousness demonstrate that the asserted claims of the '942 patent are not invalid for obviousness-type double patenting over claim 1, claim 2, claim 4, or claim 5 of the '517 patent.

6. The third sentence of 35 U.S.C. § 121 provides an exception to the rule against double patenting; it does not constitute an independent basis for asserting double patenting.

#### **IV. INDEFINITENESS**

Plaintiffs do not bear the burden of proof on indefiniteness. To the extent necessary, Plaintiffs will establish sufficient grounds to defeat Teva's allegations that claims 1, 3, and 5 of the '942 patent are invalid for indefiniteness, including as follows:

1. The phrase "substantially free" in claims 1, 3, and 5 of the '942 patent is not indefinite.

2. The phrase "substantially free" in claims 1, 3, and 5 of the '942 patent 'is amenable to construction and is not insolubly ambiguous.

3. The phrase "substantially free" in claims 1, 3, and 5 of the '942 patent can be given a reasonable meaning.

4. The person of ordinary skill in the art would understand what is claimed in claims 1, 3, and 5, of the '942 patent.

**V. ENFORCEABILITY**

Plaintiffs do not bear the burden of proof on inequitable conduct. To the extent necessary, Plaintiffs will establish sufficient grounds to defeat Teva's allegations of inequitable conduct, including as follows:

1. The '942 patent is not unenforceable due to inequitable conduct.
2. The statement in Dr. Klaus-Dieter Bremm's declaration that, "Indeed, of all of the fluoroquinolones that we have investigated, the compound of claim 25 is the best tolerated that we have ever seen" was true and accurate at the time it was made.
3. No individual with a duty of disclosure with respect to the '448 application withheld material information from the PTO or made a material misrepresentation to the PTO.
4. No individual with a duty of disclosure with respect to the '448 application acted with intent to deceive the PTO.
5. Teva has failed to prove by clear and convincing evidence that the conduct of any individual with a duty of disclosure with respect to prosecution of the '448 application is so culpable that the '942 patent should be unenforceable.

**VI. ANTICIPATION**

Plaintiffs do not bear the burden of proof on anticipation. To the extent necessary, Plaintiffs will establish sufficient grounds to defeat Teva's allegations of anticipation with respect to the '830 patent, including establishing as follows:

1. The '942 patent does not disclose each and every limitation of claim 1 of the '830 patent to a person of ordinary skill in the art.
2. The '942 patent does not disclose a "topical ophthalmic composition comprising moxifloxacin."

3. The '942 patent does not disclose the concentration range "0.1 to 1 wt%."

4. The '942 patent does not disclose a "topical ophthalmic composition comprising moxifloxacin" which is sterile, non-irritating, and free of foreign particulates.

5. The '942 patent discloses so many uses for the millions of inventive compounds, so many formulations, and so wide a range of concentrations, that a person of ordinary skill in the art would not be taught to make a "topical ophthalmic composition comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt % and pharmaceutically acceptable vehicle therefor."

6. Even if the '942 patent discloses each and every element of claim 1 of the '830 patent, it does not disclose those elements as arranged in the claim.

7. The '942 patent does not put a person of ordinary skill in the art in possession of the subject matter of claim 1 of the '830 patent.

## **VII. OBVIOUSNESS**

Plaintiffs do not bear the burden of proof on obviousness. To the extent necessary, Plaintiffs will establish sufficient grounds to defeat Teva's allegations of obviousness with respect to the '830 patent, including establishing as follows:

1. Claim 1 of the '830 patent is not invalid for obviousness.

2. Claim 1 of the '830 patent is not *prima facie* obvious in light of the art on which Teva relies.

3. Teva has not proven by clear and convincing evidence that the invention claimed in the '830 patent would have been obvious to the person of ordinary skill in the art as of September 30, 1998 in light of the scope and content of the prior art, the differences between

each asserted claim and the prior art, the level of ordinary skill in the art at that time, the properties of the claimed compounds, and objective indicia of nonobviousness.

4. The problem addressed by the '830 patent was to provide "improved compositions . . . based on the use of antibiotics that are more effective than existing antibiotics against key ophthalmic pathogens, and less prone to the development of resistance by those pathogens." '830 patent, col. 1, ll. 23-52.

5. The person of ordinary skill in the art would have had no reason as of September 30, 1998 to select moxifloxacin for use in a topical ophthalmic composition to solve the problems associated with the then state of the art fluoroquinolones.

6. A person of ordinary skill in the art attempting to solve the problems addressed in the '830 patent would not have had reason to look to the '942 patent or any other reference relied upon by Teva.

7. The relative lack of potency of moxifloxacin against key ocular pathogens, the lack of an expectation that a topical ophthalmic composition with moxifloxacin would penetrate better than ofloxacin into the important ocular tissues, the resistance concerns with fluoroquinolones, and the toxicity concerns with fluoroquinolones would have taught away from making a topical ophthalmic composition with moxifloxacin.

8. Vigamox® and other compositions within the scope of claim 1 demonstrate objective indicia of non-obviousness, including unexpected desirable properties, satisfaction of a long-felt but unmet need, earning praise from practitioners in the field, and commercial success.

#### **VIII. NON-ENABLEMENT**

Plaintiffs do not bear the burden of proof on non-enablement. To the extent necessary, Plaintiffs will establish sufficient grounds to defeat Teva's allegations of non-enablement with respect to the '830 patent, including establishing as follows:

1. The '830 patent enables a person of ordinary skill to make and use a topical ophthalmic composition comprising moxifloxacin as recited in claim 1 of the '830 patent without undue experimentation.

#### **IX. BEST MODE**

Plaintiffs do not bear the burden of proof on best mode. To the extent necessary, Plaintiffs will establish sufficient grounds to defeat Teva's allegations that the '830 patent does not satisfy the best mode requirement, including establishing as follows:

1. The inventors of the '830 patent did not have a subjective best mode of practicing the invention as recited in claim 1 of the '830 patent as of September 30, 1998.

2. Teva's allegation that the use of the hydrochloride salt of moxifloxacin constituted the best mode of the inventors for practicing the invention is factually and legally incorrect. The inventors preferred a topical ophthalmic solution containing moxifloxacin, but had no preference for any particular form of moxifloxacin (including moxifloxacin hydrochloride) to use as a starting material to make the preferred formulation.

3. To the extent that the inventors had a best mode as of September 30, 1998, it was disclosed in sufficient detail to allow one of skill in the art to practice the best mode without undue experimentation.



**X. LACK OF WRITTEN DESCRIPTION**

Plaintiffs do not bear the burden of proof on lack of written description. To the extent necessary, Plaintiffs will establish sufficient grounds to defeat Teva's allegations of lack of written description, including establishing as follows:

1. The '830 patent describes to a person of ordinary skill in the art a topical ophthalmic composition comprising moxifloxacin as recited in claim 1 of the '830 patent to put a person of ordinary skill in the art in possession of said composition as claimed.
2. Moxifloxacin functions as a preservative because the compound is self-preserving.
3. Because "preservatives" (apart from moxifloxacin) are not a limitation recited in claim 1 of the '830 patent, it is not relevant whether embodiments in the written description are disclosed with or without "preservatives" (apart from moxifloxacin).
4. The specification discloses embodiments of claim 1 of the '830 patent with and without a preservative (other than moxifloxacin).

**XI. RELIEF**

Plaintiffs intend to establish that:

1. A judgment should be entered providing that the effective date of any FDA approval for Teva commercially to make, use, or sell moxifloxacin or any pharmaceutically utilizable acid addition salt thereof, the drug product that is the subject of ANDA No. 77-437, or any drug product containing moxifloxacin or any pharmaceutically utilizable acid addition salt thereof be not earlier than the latest of the expiration dates of the '517 and '942 patents.
2. A judgment should be entered providing that the effective date of any FDA approval for Teva commercially to make, use, or sell the drug product that is the subject of

ANDA No. 78-073 or any topical ophthalmic pharmaceutical composition comprising moxifloxacin or any pharmaceutically useful acid addition salt thereof in a concentration of 0.1 to 1.0 wt % and pharmaceutically acceptable vehicle therefor be not earlier than the latest of the expiration dates of the '517, '942, and '830 patents.

3. Teva should be enjoined from infringing or inducing the infringement of the '517, '942, and '830 patents.

4. This is an exceptional case within the meaning of 35 U.S.C. § 285, warranting an award of reasonable attorneys' fees to Plaintiffs.

5. Plaintiffs should be awarded costs.

# EXHIBIT 11

Exhibit 11: Teva's Brief Statement of Intended Proofs

**EXHIBIT 11**

**TEVA'S BRIEF STATEMENT OF INTENDED PROOFS**

**I. U.S. PATENT 4,990,517**

**A. Claim Construction**

1. The compounds defined by the preamble and the formula presented in claims 1, 2, 8, 9, and 11 of the '517 patent do not encompass a single enantiomer, or a mixture of a single enantiomer and its mirror image compound, other than as a racemate.

**B. Noninfringement**

Teva does not bear the burden of proof with respect to infringement. To the extent necessary, Teva will establish sufficient grounds to defeat Plaintiffs' allegations that the asserted claims of the '517 patent are infringed, including as follows:

1. If the asserted claims of the '517 patent are construed as Teva advocates, then the drug product that is the subject of Teva's ANDA No. 77-437 does not, and will not, infringe claims 1, 2, 8, or 9 of the '517 patent because the active pharmaceutical ingredient in Teva's drug product is not a racemate.

2. If the asserted claims of the '517 patent are construed as Teva advocates, then the use of the drug product that is the subject of Teva's ANDA No. 77-437 in accordance with any label submitted in Teva's ANDA No. 77-437 does not, and will not, infringe claims 1, 2, 8, 9, or 11 of the '517 patent because the active pharmaceutical ingredient in Teva's drug product is not a racemate.

3. If the asserted claims of the '517 patent are construed as Teva advocates, then the drug product that is the subject of Teva's ANDA No. 78-073 does not, and will not, infringe claims 1, 2, or 8 of the '517 patent because the active pharmaceutical ingredient in Teva's drug product is not a racemate.

4. If the asserted claims of the '517 patent are construed as Teva advocates, then the use of the drug product that is the subject of Teva's ANDA No. 78-073 in accordance with any label submitted in Teva's ANDA No. 78-073 does not, and will not, infringe claims 1, 2, 8, or 11

Exhibit 11: Teva's Brief Statement of Intended Proofs

of the '517 patent because the active pharmaceutical ingredient in Teva's drug product is not a racemate.

**II. U.S. PATENT 5,607,942**

**A. Claim Construction**

1. The term "said compound substantially free of other enantiomers and stereoisomers," in claims 1, 3, and 5 of the '942 patent, to the extent it can be understood, means that any impurities consisting of "other enantiomers" or "other stereoisomers" must be present in an amount below the detection limit for such enantiomers or stereoisomers.

2. The compounds defined by the preamble and the formula presented in claims 2, 4, and 7 of the '942 patent do not encompass a single enantiomer, or a mixture of a single enantiomer and its mirror image compound, other than as a racemate.

**B. Noninfringement**

Teva does not bear the burden of proof with respect to infringement. To the extent necessary, Teva will establish sufficient grounds to defeat Plaintiffs' allegations that the asserted claims of the '942 patent are infringed, including as follows:

1. If the asserted claims of the '942 patent are construed as Teva advocates, then the drug product that is the subject of Teva's ANDA No. 77-437 does not, and will not, infringe claims 1, 2, 3, or 4 of the '942 patent because the active pharmaceutical ingredient in Teva's drug product is not a racemate and because the active pharmaceutical ingredient includes the R,R enantiomer such that it is not "substantially free of other enantiomers."

2. If the asserted claims of the '942 patent are construed as Teva advocates, then the use of the drug product that is the subject of Teva's ANDA No. 77-437 in accordance with any label submitted in Teva's ANDA No. 77-437 does not, and will not, infringe claims 1, 2, 3, 4, 5, or 7 of the '942 patent because the active pharmaceutical ingredient in Teva's drug product is not a racemate and because the active pharmaceutical ingredient includes the R,R enantiomer such that it is not "substantially free of other enantiomers."

3. If the asserted claims of the '942 patent are construed as Teva advocates, then the drug product that is the subject of Teva's ANDA No. 78-073 does not, and will not, infringe claims 1, 2, 3, or 4 of the '942 patent because the active pharmaceutical ingredient in Teva's

## Exhibit 11: Teva's Brief Statement of Intended Proofs

drug product is not a racemate and because the active pharmaceutical ingredient includes the R,R enantiomer such that it is not "substantially free of other enantiomers."

4. If the asserted claims of the '942 patent are construed as Teva advocates, then the use of the drug product that is the subject of Teva's ANDA No. 78-073 in accordance with any label submitted in Teva's ANDA No. 78-073 does not, and will not, infringe claims 1, 2, 3, 4, 5, or 7 of the '942 patent because the active pharmaceutical ingredient in Teva's drug product is not a racemate and because the active pharmaceutical ingredient includes the R,R enantiomer such that it is not "substantially free of other enantiomers."

### **C. Invalidity**

#### **i. Indefiniteness**

Claims 1, 3, and 5 of the '942 patent are indefinite and therefore invalid under 35 U.S.C. § 112, second paragraph for any of the following reasons:

1. The term "said compound substantially free of other enantiomers and stereoisomers" in claims 1, 3, and 5 of the '942 patent would not be understood by a person of ordinary skill in the art.
2. Nothing in the '942 patent's specification or prosecution history, nor the prior art, provides any indication as to what is covered by the term "said compound substantially free of other enantiomers and stereoisomers" in claims 1, 3, and 5 of the '942 patent so as to adequately notify the public of the scope of the patentee's right to exclude.
3. The construction of the term "said compound substantially free of other enantiomers and stereoisomers" in claims 1, 3, and 5 of the '942 patent that Plaintiffs advocate (i.e., "largely, but not necessarily free" of other enantiomers and stereoisomers), provides no further guidance as to the scope of the claim than the plain language of the claim itself and does not adequately notify the public of the scope of the patentee's right to exclude.
4. The construction of the term "said compound substantially free of other enantiomers and stereoisomers" in claims 1, 3, and 5 of the '942 patent that Plaintiffs advocate (i.e., "largely, but not necessarily free" of other enantiomers and stereoisomers) is not a reasonable meaning of the term.

Exhibit 11: Teva's Brief Statement of Intended Proofs

**ii. Non-Statutory Double Patenting**

1. Claims 1, 2, 3, 4, 5, and 7 of the '942 patent are invalid for non-statutory double patenting per *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003)<sup>1</sup>.

2. The patent application giving rise to the '942 patent (U.S. Patent Application 08/406,448 ("the '448 application")) was filed as a divisional of application Ser. No. 07/737,631, which was filed as a divisional of application Ser. No. 07/580,906, which was filed as a divisional of application Ser. No. 07/375,434 ("the '434 application"), which issued as the '517 patent.

3. The U.S. Patent and Trademark Office issued a restriction requirement during prosecution of the '434 application, in response to which Bayer elected a group (Restriction Group IV), and the '517 patent issued with claims from Restriction Group IV of the restriction requirement.

4. Claims 1, 2, 3, 4, 5, and 7 of the '942 patent fall within Restriction Group IV of the '434 application; thus the '448 application was not filed in consonance with the restriction requirement imposed in the '434 patent and, as such, is not a proper divisional application in accordance with 35 U.S.C. § 121.

5. The limitations of claims 1, 2, 3, 4, 5, and 7 of the '942 patent were presented by Bayer as individual members of Markush groupings within the subject matter of Restriction Group IV of the '434 application. Restriction Group IV was classified in Class 546, subclass 113, as is both the '517 patent and the '942 patent. Thus, claims 1, 2, 3, 4, 5, and 7 of the '942 patent are not patentably distinct from the '517 patent.

6. Objective evidence of non-obviousness is not relevant to an inquiry into non-statutory double patenting.

**iii. Unenforceability**

1. The '942 patent was obtained through inequitable conduct, and thus the '942 patent is unenforceable.

---

<sup>1</sup> Teva does not base its double patenting contention on *In re Schneller*, 397 F.2d 350 (C.C.P.A. 1968).



## Exhibit 11: Teva's Brief Statement of Intended Proofs

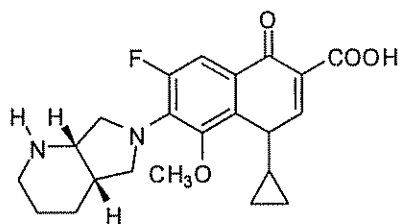
2. Dr. Klaus-Dieter Bremm consulted with Dr. Uwe Petersen (a co-inventor of the '942 patent) in drafting a declaration executed by Dr. Bremm on July 20, 1995 and which was submitted to the U.S. Patent and Trademark Office on or about September 21, 1995 in support of the prosecution of Bayer's U.S. Patent Application Serial No. 08/406,448 ("the '448 application"), which eventually issued as the '942 patent.

3. Dr. Bremm's declaration presented purported superior properties of the compositions of the claims pending in the '448 patent; Dr. Bremm intended his declaration to respond to questions raised by the Patent Office in connection with the examination of the '448 application.

4. Among the statements in his declaration, Dr. Bremm stated, "of all the fluoroquinolones that we have investigated, the compound of claim 25 is the best tolerated that we have ever seen." Drs. Bremm and Peterson discussed the language to be used for this statement.

5. After reviewing the declaration, the Examiner at the U.S. Patent and Trademark Office agreed that the "showing of unexpected results overcomes the obviousness-type rejection," and, as a result, allowed claim 25 (which issued as claim 1 of the '942 patent).

6. As of July 20, 1995, Drs. Bremm and Peterson knew that a compound referred to internally at Bayer as Bay Y 6957 had been investigated at Bayer. Moreover, Drs. Bremm and Peterson knew the chemical structure of Bay Y 6957 to be:



which is a betaine (i.e., zwitterion or free amine), the hydrochloride salt of which was referred to internally at Bayer as Bay 12-8039. As of July 20, 1995, Drs. Bremm and Peterson also knew that Bay 12-8039 had been investigated at Bayer.

7. As of July 20, 1995, Drs. Bremm and Peterson knew that both the betaine (i.e., Bay Y 6957) and its hydrochloride salt (i.e., Bay 12-8039) were compounds of claim 25 then pending in the '448 application. Claim 25 also included a large number of other compounds

## Exhibit 11: Teva's Brief Statement of Intended Proofs

relating to the betaine, specifically an "alkali metal, alkaline earth metal, silver or guanidinium salt thereof or a pharmaceutically utilizable hydrate or acid addition salt thereof."

8. In June, 1993, Drs. Bremm and Peterson had participated in a meeting at Bayer at which it was revealed that the results of Bayer's investigations concerning Bay Y 6957 (i.e., the betaine) was that this betaine compound showed "surprisingly poor tolerability" in test animals, and that, for this reason, the betaine was not recommended as a candidate for clinical development.

9. In contrast to the surprisingly poor tolerability exhibited by the Bay Y 6957 (i.e., the betaine), certain of its salts demonstrated improved tolerability. As of July 20, 1995, Drs. Bremm and Peterson knew that only one of those salts – the hydrochloride salt (i.e., Bay 12-8039) – was the best tolerated compound.

10. Dr. Bremm intended that the declaration he signed inform the U.S. Patent and Trademark Office only of the tolerability of this best-tolerated hydrochloride salt (i.e., Bay 12-8039), which is but one of many compounds embraced by the claim 25 referred to in the declaration. Dr. Bremm, thus, intended not to inform the U.S. Patent and Trademark Office about the results of Bayer's investigation of any other compounds of claim 25, such as Bay Y 6957 (i.e., the betaine), and the declaration (nor any other portion of the file history of the '942 patent) did not disclose the poor tolerability of the betaine.

11. By not disclosing the "surprisingly poor tolerability" of Bay Y 6957, Drs. Bremm and Peterson misrepresented "the compound of claim 25" to have the superior properties of but one cherry-picked compound (i.e., Bay 12-8039) from among the many compounds of claim 25 and hid the poor tolerability of the betaine (Bay Y 6957) from the scrutiny of the Examiner at the U.S. Patent and Trademark Office charged with examining the '448 application.

12. Because of Drs. Bremm's and Peterson's intentional omission of their knowledge of the tolerability of other compounds of claim 25 – especially the "surprisingly poor tolerability" of the betaine – the Examiner at the U.S. Patent and Trademark Office based his conclusion concerning Bayer's showing of unexpected results – and his allowance of the application – on their material misrepresentation.

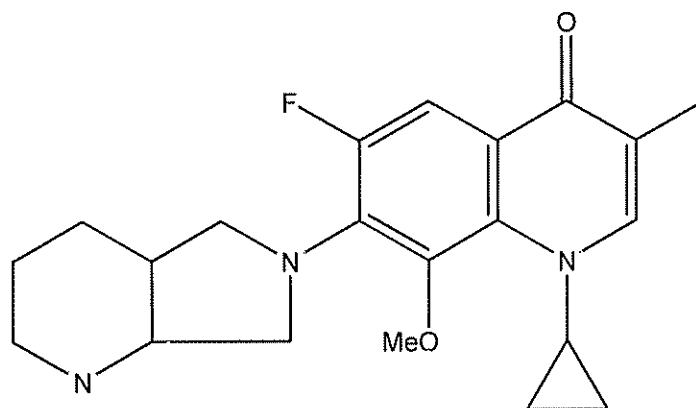
## Exhibit 11: Teva's Brief Statement of Intended Proofs

13. Drs. Bremm's and Peterson's material misrepresentation was intentional, and it violated the duty of candor that owed to the U.S. Patent and Trademark Office under 37 C.F.R. § 1.56.

### III. U.S. PATENT 6,716,830

#### A. Claim Construction

1. The term "moxifloxacin" in claim 1 of the '830 patent is as defined by the '830 patent to mean a compound of the formula:



#### B. Noninfringement

Teva does not bear the burden of proof with respect to infringement. To the extent necessary, Teva will establish sufficient grounds to defeat Plaintiffs' allegations that claim 1 of the '830 patent is infringed, including as follows:

1. If claim 1 of the '830 patent is construed as Teva advocates, then the drug product that is the subject of Teva's ANDA No. 78-073 does not, and will not, infringe claim 1 of the '830 patent.

2. If claim 1 of the '830 patent is construed as Teva advocates, then the use of the drug product that is the subject of Teva's ANDA No. 78-073 in accordance with any label submitted in Teva's ANDA No. 78-073 does not, and will not, infringe claim 1 of the '830 patent.

## Exhibit 11: Teva's Brief Statement of Intended Proofs

**C. Invalidity****i. Anticipation**

1. If Plaintiffs' construction of claim 1 of the '830 patent is adopted, then claim 1 of the '830 patent is anticipated by the '942 patent, which is prior art to the '830 patent under 35 U.S.C. § 102(b), and therefore claim 1 of the '830 patent is invalid.

**ii. Obviousness**

1. If Plaintiffs' construction of claim 1 of the '830 patent is adopted, then claim 1 of the '830 patent would have been obvious to a person of ordinary skill in the art under 35 U.S.C. § 103(a).

2. Any one of the following establishes *prima facie* obviousness of claim 1 of the '830 patent:

- The '942 patent;
- The prosecution history of the '942 patent;
- The '942 patent, in light of the formulation of Ocuflox® Ophthalmic Solution;
- The '942 patent, in light of the formulation of Tobradex® Ophthalmic Suspension;
- The '942 patent, in light of the formulation of Ciloxan® Ophthalmic Ointment;
- The '942 patent, in light of the formulation of Ciloxan® Ophthalmic Solution;
- The '942 patent, in light of U.S. Patent No. 5,149,693;
- The '942 patent, in light of Firestone, B.A. et al., "Solubility characteristics of three fluoroquinolone ophthalmic solutions in an in vitro tear model," Int'l Journal of Pharmaceutics 164 (1998) 119-128;
- The '942 patent, in light of Schmitz et al., "Relationship between ciprofloxacin, ofloxacin, levofloxacin, sparfloxacin and moxifloxacin (BAY 12-8039) MICs and mutations in *grlA*, *grlB*, *gyrA*, and *gyrB* in 116 unrelated clinical isolates of *Staphylococcus aureus*," J. Antimicrob. Chemother., Vol. 41, pp. 481-484;
- The '942 patent, in light of Dalhoff et al., "In vitro activity of BAY 12-8039, a new 8-methoxyquinolone," Chemotherapy, Vol. 42, No. 6, pp. 410-425 (1996);

## Exhibit 11: Teva's Brief Statement of Intended Proofs

- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of the '942 patent;
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of the formulation of Ciloxan® Ophthalmic Solution;
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of the formulation of Ciloxan® Ophthalmic Ointment;
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of the formulation of Ocuflox® Ophthalmic Solution;
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of the formulation of Tobradex® Ophthalmic Suspension;
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of U.S. Patent No. 5,149,693;
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light Firestone, B.A. et al., "Solubility characteristics of three fluoroquinolone ophthalmic solutions in an in vitro tear model," Int'l Journal of Pharmaceutics 164 (1998) 119-128;
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of Schmitz et al., "Relationship between ciprofloxacin, ofloxacin, levofloxacin, sparfloxacin and moxifloxacin (BAY 12-8039) MICs and mutations in *grlA*, *grlB*, *gyrA*, and *gyrB* in 116 unrelated clinical isolates of *Staphylococcus aureus*," J. Antimicrob. Chemother., Vol. 41, pp. 481-484;
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of Dalhoff et al., "In vitro activity of BAY 12-8039, a new 8-methoxyquinolone," Chemotherapy, Vol. 42, No. 6, pp. 410-425 (1996);
- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of Ciloxan®, Ocuflox®, and Schmitz et al., "Relationship between ciprofloxacin, ofloxacin, levofloxacin, sparfloxacin and moxifloxacin (BAY 12-

Exhibit 11: Teva's Brief Statement of Intended Proofs

8039) MICs and mutations in *grlA*, *grlB*, *gyrA*, and *gyrB* in 116 unrelated clinical isolates of *Staphylococcus aureus*," *J. Antimicrob. Chemother.*, Vol. 41, pp. 481-484; or

- A Bayer poster entitled "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone" in light of Ciloxan®, Ocuflax®, and Dalhoff et al., "In vitro activity of BAY 12-8039, a new 8-methoxyquinolone," *Chemotherapy*, Vol. 42, No. 6, pp. 410-425 (1996).

3. Teva does not bear the burden of demonstrating a lack of secondary considerations of non-obviousness. To the extent necessary, Teva will establish sufficient grounds to defeat Plaintiffs' evidence of secondary considerations, including that Plaintiffs' evidence of secondary considerations is not commensurate with the scope of claim 1 of the '830 patent and is therefore not probative of the nonobviousness of claim 1 of the '830 patent.

**iii. Lack of Written Description**

1. Claim 1 of the '830 patent is broader than the supporting disclosure because claim 1 does not contain a limitation requiring a preservative separate from moxifloxacin, which the specification of the '830 patent states is required.

2. Thus, the written description of the '830 patent does not convey that the inventors of the '830 patent were in possession of the invention of claim 1 as of the filing date of the '830 patent.

3. The '830 patent, therefore, does not contain an adequate written description of claim 1 of the '830 patent and is invalid under 35 U.S.C. § 112, first paragraph.

**iv. Lack of Enablement**

1. If the court agrees with Alcon's definition of the skill possessed by a person of ordinary skill in the art, then claim 1 of the '830 patent does not enable such a person to make the claimed composition without undue experimentation.

2. The '830 patent contains no discussion concerning how to make the claimed ophthalmic formulations. Unless the person of ordinary skill in the art were experienced in the art of formulating topical ophthalmic compositions, undue experimentation would be required to make the claimed composition.

Exhibit 11: Teva's Brief Statement of Intended Proofs

3. Accordingly, claim 1 of the '830 patent is not enabled and is invalid under 35 U.S.C. § 112, first paragraph.

**v. Failure to Set Forth the Inventors' Best Mode**

1. Dr. David Stroman, one of the inventors of the '830 patent, conceived only of using moxifloxacin hydrochloride as the active agent in the ophthalmic formulation of claim 1 of the '830 patent.

2. Thus, the use of moxifloxacin hydrochloride was Dr. Stroman's best mode for practicing the invention.

3. The '830 patent does not disclose the use of moxifloxacin hydrochloride and, thus, the '830 patent invalid under 35 U.S.C. § 112, first paragraph, for failing to set forth Dr. Stroman's best mode for practicing the invention.

**IV. EXCEPTIONAL CASE**

1. Plaintiffs' assertion of the '942 patent, which was obtained through inequitable conduct, renders this case "exceptional" under 35 U.S.C. § 285.

2. Alcon's assertion of the '830 patent against Teva in this action is unjustified such that this case "exceptional" under 35 U.S.C. § 285.

**V. RELIEF**

Teva intends to establish that:

1. A judgment should be entered providing that the drug product that is the subject of Teva's ANDA No. 77-437 does not, and will not, infringe the '517 patent or the '942 patent.

2. A judgment should be entered providing that the use of the drug product that is the subject of Teva's ANDA No. 77-437 in accordance with any label submitted in Teva's ANDA No. 77-437 does not, and will not, infringe the '517 patent or the '942 patent.

3. A judgment should be entered providing that the drug product that is the subject of Teva's ANDA No. 78-073 does not, and will not, infringe the '517 patent, the '942 patent, or the '830 patent.



Exhibit 11: Teva's Brief Statement of Intended Proofs

4. A judgment should be entered providing that the use of the drug product that is the subject of Teva's ANDA No. 78-073 in accordance with any label submitted in Teva's ANDA No. 78-073 does not, and will not, infringe the '517 patent, the '942 patent, or the '830 patent.

5. A judgment should be entered providing that claims 1, 3, and 5 of the '942 patent are indefinite and therefore invalid under 35 U.S.C. § 112, second paragraph.

6. A judgment should be entered providing that claims 1, 2, 3, 4, 5, and 7 of the '942 patent are invalid for non-statutory double patenting.

7. A judgment should be entered providing that the '942 patent is unenforceable due to inequitable conduct during prosecution of the application leading to the '942 patent.

8. A judgment should be entered providing that claim 1 of the '630 patent is invalid under 35 U.S.C. § 102(b).

9. A judgment should be entered providing that claim 1 of the '630 patent is invalid under 35 U.S.C. § 103(a).

10. A judgment should be entered providing that claim 1 of the '630 patent is invalid under 35 U.S.C. § 112, first paragraph.

11. A judgment should be entered providing that this case is exceptional under 35 U.S.C. § 285, warranting an award of reasonable attorney's fees to Teva.

12. Teva should be awarded costs.



# EXHIBIT 12

**EXHIBIT 12**

**PLAINTIFFS' LIST OF MISCELLANEOUS ISSUES FOR THE PRETRIAL  
CONFERENCE**

Bayer and Alcon intend to raise the following issues at the Pretrial Conference:

1. Scheduling of trial.
2. Amount of time per side.
3. Order in which the parties will present their respective cases.
4. Order of testimony from Plaintiffs' expert witnesses.
5. The unavailability of Dr. Uwe Petersen, an inventor of two of the patents-in-suit who has been accused of inequitable conduct.

# EXHIBIT 13

**Exhibit 13**

**TEVA'S LIST OF MISCELLANEOUS ISSUES FOR THE PRETRIAL CONFERENCE**

Teva intends to raise the following issues at the Pretrial Conference:

1. The order of proofs.
2. The order of the parties' opening statements.
3. The length of the trial.
4. Whether deposition designations shall be read into evidence for adverse

witnesses, including expert witnesses, who are present at the trial or who are expected to testify live.

5. Whether testimony from the previous Bayer v. Dr. Reddy's Laboratories trial should be treated as deposition testimony from this case is to be treated, and read into evidence in the same manner.

6. Whether the Courtroom shall be closed during testimony involving Highly Confidential or Confidential information.